A. The Appropriate Market is the U.S. Memantine Drug Market

An initial step in antitrust claim analysis requires identification of the market, which consists of a relevant product and geographic market. PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 105 (2d Cir. 2002) (components of market definition); Geneva Pharm. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004) (market definition is the initial step to both Section 1 and Section 2 claims). A relevant geographic market is the area "in which the seller operates and where consumers can turn, as a practical matter, for supply of the relevant product." United States v. Eastman Kodak Co., 63 F.3d 95, 104 (2d Cir. 1995). A relevant product market "is composed of products that have reasonable interchangeability for the purposes for which they are produced—price, use and qualities considered." United States v. E. I. Du Pont de Nemours & Co., 351 U.S. 377, 404 (1956). As the geographic market is not in dispute here, definition of the product market is the relevant inquiry. FOF ¶ 70.

In defining the market, courts consider the choices available to consumers in the market. See Eastman Kodak Co. v. Image Tech. Servs., 504 U.S. 451, 482 (1992) citing United States v. Grinnell Corp., 384 U.S., at 572. Courts consider

"practical indicia [such as] industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price change, and specialized vendors." See Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962). Cross-elasticity of demand is a common empirical methodology used to determine whether two or more products comprise the same market. See e.g. Bogan v. Hodgkins, 166 F.3d 509, 516 (2d Cir. 1999) citing Brown Shoe, 370 U.S. at 325; Chapman v. New York State Div. for Youth, 546 F.3d 230, 238 (2d Cir. 2008); Hayden Pub. Co. v. Cox Broad. Corp., 730 F.2d 64, 71 (2d Cir. 1984). The cross-elasticity of demand calculation measures change in sales of a product to price changes of a potential substitute. E. I. du Pont, 351 U.S. at 400. A high cross-elasticity of demand suggests substitutability, while a low one does not; consumers will respond to an increase in the price of one product by purchasing the relatively inexpensive second product only if the two products are substitutes. See id. As a result, two products with high cross-elasticity of demand are properly grouped into the same market since they are substitutes. Id.

A single product may constitute a relevant market where there are no reasonably interchangeable substitutes. See Image Tech., 504 U.S. at 481-82. To be a substitute product for purposes of product market definition, customers must be willing to switch to a competitive product as a result of a price change. United States v. H&R Block, Inc., 833 F. Supp. 2d 36 (D.D.C. 2011).

As in this instance, courts have found a single brand-name drug and its generic equivalents to be a relevant product market in cases where the challenged conduct involves a branded drug manufacturer's effort to exclude generic competition. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 377-88 (D. Mass. 2013) ("The fact that other drugs may be used to treat heartburn and related conditions is immaterial to the present inquiry."); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fl. 2005).

The facts found above establish the State's contention that the appropriate product market in this case is the nationwide memantine market. See generally FOF § IV. CIs and memantine are not considered substitutes nor are they prescribed

as such by physicians. FOF ¶¶ 58, 62. CIs are used to treat patients with mild-stage Alzheimer's while memantine is not indicated for such patients, and the two types of drugs are predominantly complements rather than supplements. FOF ¶ 57.

Defendants' contention that the appropriate product market should include CIs is not well supported by the evidence. As found above, Defendants' cross elasticity of demand analysis was less convincing than the State's. FOF ¶ 67. Industry categorizations of memantine and CIs as part of the "Alzheimers' Drug Market" or an "anti-dementia" category do not alter the observable behavior of patients and physicians, as reflected in the cross elasticity of demand analyses summarized above. See FOF § IV.B. Categorizations in this instance may not be based on substitutability, but rather serve as umbrella terms encompassing distinct product markets: akin to, perhaps, categorizing two distinct non-substitutable products such as a sponge and soap under the umbrella of cleaning supplies. Similarly, the fact that both CIs and memantine tablets can be produced using the same machinery and sold along the same distribution channels does not establish substitutability. Adopting Defendants' contention, tablet forms of dissimilar medicines, for example heart medication and statins, may be

considered substitutes because they can be made on the same machines and distributed along the same sales channels.

The appropriate geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States.

B. The Defendant's Monopoly Power

To establish a claim of unlawful monopolization under Section 2 of the Sherman Act, the State must show that Defendants: (a) have monopoly power in a relevant market and; (b) acquired or maintained such monopoly power through anticompetitive exclusionary conduct. See Grinnell, 384 U.S. at 570-71. To establish a claim of unlawful attempted monopolization under Section 2 of the Sherman Act, the State must show that Defendants: (1) engaged in anticompetitive behavior; (2) with specific intent to monopolize; and (3) with a dangerous probability of achieving monopoly power. Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993); PepsiCo, 315 F.3d at 105 (2d Cir. 2002). The two claims are substantially identical, with the exception that attempted monopolization requires a showing of specific intent to

monopolize. The remaining elements can be addressed jointly. Exclusionary behavior under the monopolization claim and anticompetitive conduct under the attempted monopolization claim overlap. The first monopolization and the third attempted monopolization elements vary only by degree. See Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 100 (2d Cir. 1998) ("the same concept of market power as that used in a completed monopolization claim [applies] . . . [though] a lesser degree of market power may establish an attempted monopolization claim than that necessary to establish a completed monopolization claim").

Having established that the relevant market is the nationwide memantine market, the issue is whether Defendants have monopoly power in the relevant market, i.e., "the ability to control prices or exclude competition." United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956); PepsiCo, 315 F.3d at 107. While a "patent does not of itself establish a presumption of market power in the antitrust sense," In re Indep. Serv. Organizations Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000), a high market share is an indication of monopoly power. Tops Markets, 142 F.3d at 98 (quoting Broadway Delivery Corp. v. United Parcel Serv. of

America, Inc., 651 F.2d 122, 129 (2d Cir.1981) ("the higher a market share, the stronger is the inference of monopoly power"). A complete market power analysis considers market share in light of the relevant market's particular characteristics, including "strength of the competition, the probable development of the industry, the barriers to entry, the nature of the anticompetitive conduct and the elasticity of consumer demand." Id. citing Int'l Distribution Centers, Inc. v. Walsh Trucking Co., 812 F.2d 786, 792 (2d Cir. 1987); see also Hayden, 730 F.2d at 69 citing United States v. Columbia Steel Co., 334 U.S. 495, 527 (1948). Market power may also be established by considering evidence of anticompetitive effects of the challenged conduct. FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 460-61 (1986) ("proof of actual detrimental effects . . . can obviate the need for an inquiry into market power, which is but a surrogate for detrimental effects."); Geneva Pharms, 386 F.3d at 509; Tops Markets, 142 F.3d at 98 (market power may be proven by direct evidence of anticompetitive effects); Todd v. Exxon Corp., 275 F.3d 191, 206 (2d Cir. 2001) ("If a plaintiff can show that a defendant's conduct exerted an actual adverse effect on competition, this is a strong indicator of market power.").

As established by the facts found above, prior to generic entry into the market, Defendants are the exclusive producers of all forms of memantine. FOF ¶ 41. Until that time, Defendants control price and distribution for memantine, and have a patent-protected right to exclude all competition. FOF ¶ 126. As CIs are not indicated for moderate to severe Alzheimer's patients, most patients in that group have no alternative to memantine. FOF ¶ 57. Prior to July 2015, Defendants have 100% of the market, there is no competition, development is controlled by Defendants, Defendants' patent are absolute barriers to entry, and demand is inelastic: Defendants have monopoly power. See generally FOF § IV.

Starting in July 2015, however, several generic manufacturers enter the memantine market and Defendants' memantine market share is projected to drop below 100%. See FOF ¶¶ 126-27, 136. Determining whether Defendants will continue to enjoy monopoly power following generic entry requires projections of future conditions in the memantine market. [redacted] FOF ¶ 147. At minimum, this conflict establishes that a serious question exists as to whether

Defendants will control sufficient market share to qualify as strong evidence of monopoly power. As found above, Defendants projected control of [redacted] of the memantine market ([redacted] with XR and [redacted] with the upcoming fixed dose combination) in 2016. FOF ¶ 139. This is a considerable market share, indeed "a share above 70% is usually strong evidence of monopoly power." Broadway Delivery Corp. v. United Parcel Serv. of Am., Inc., 651 F.2d 122, 129 (2d Cir. 1981).

Moreover, depending on other market factors, courts in the Second Circuit have permitted findings of market power with shares less than 50%. See United States v. Visa USA, Inc., 344 F.3d 229, 240 (2d Cir. 2003) (MasterCard found to have market power with 26% market share); Broadway Delivery, 651 F.2d at 129 ("the jury should not be told that it must find monopoly power lacking below a specified share or existing above a specified share"); In re Payment Card Interchange Fee & Merchant Discount Antitrust Litig., 562 F. Supp. 2d 392, 400 (E.D.N.Y. 2008) (a finding of market share less than 30% would not foreclose the possibility of proving monopoly power).

In the hard switch scenario, Defendants' generic competitors will be limited to the [redacted] of the memantine market

not controlled by XR and the anticipated FDC Namenda product. FOF ¶ 139. The switch-resistant Namenda users already taking XR, i.e., the majority of all memantine users at the time of generic entry, will likely exhibit the same resistance to adopting generic IR as exhibited by current IR patients resisting XR. FOF ¶¶ 85, 154. Physician and health plan hesitations to change their patients' medications will exacerbate this inertia. FOF ¶¶ 143-45, 155.

Defendants' dominance in the memantine market creates an adverse effect on memantine pricing and competition. FOF ¶ 117. Non-AB-rated generic drugs are not able to compete effectively for sales of a branded drug in the same class, even if the price of the generics is much lower than the brand. FOF ¶ 133. The Lipitor example, where the absence of AB-substitution limited a generic to only 30% of the market, is illustrative. FOF ¶ 133. Furthermore, generic drugs are typically not marketed to physicians or patients. FOF ¶ 128. Defendants' conduct, by emphasizing the more expensive patent-protected formulations of memantine and eliminating distribution of the Namenda IR formulation subject to generic substitution laws, may therefore significantly alter the average price of memantine in the market. FOF ¶ 117.

The evidence found above, while not definitive, adequately establishes a substantial question as to whether Defendants have monopoly power over the relevant market.

C. Anticompetitive Conduct by Defendants

While the mere possession of monopoly power is not unlawful, monopolists cannot run their businesses in an anticompetitive manner. See e.g., Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); United States v. Microsoft, 253 F.3d 34, 64 (D.C. Cir. 2001); C.R. Bard, Inc. v. M3 Sys., 157 F.3d 1340 (Fed. Cir. 1998); United States v. Dentsply Int'l, 399 F.3d 181 (3d Cir. 2005).

The central inquiry is whether "a monopoly [is] engaging in exclusionary conduct as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Microsoft Corp., 253 F.3d at 58 quoting Grinnell, 384 U.S. at 571; see also Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 274 (2d Cir. 1979); Port Dock & Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 124 (2d Cir. 2007); In re Adderall XR Antitrust Litig., 754 F.3d 128,

133 (2d Cir. 2014), as corrected (June 19, 2014); cf. United States v. Colgate & Co., 250 U.S. 300, 307 (1919) ("In the absence of any purpose to create or maintain a monopoly, the [Sherman] act does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal) (emphasis added).

A monopolist's decision to withdraw a product from customers may violate antitrust laws if done for the sole purpose of harming competition, i.e., if it constitutes exclusionary conduct. See e.g., Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 424 (D. Del. 2006) (defendant's decision to withdraw a prior drug formulation of TriCor in an effort to shift patients to a new one and exclude generic competition may be exclusionary); Xerox Corp. v. Media Scis. Int'l., 511 F. Supp. 2d 372, 388 (S.D.N.Y. 2007) (discontinued and redesigned printer models to "foreclose all other competition, and not to improve the product" may be exclusionary); Glen Holly Entm't v. Tektronix Inc., 352 F.3d 367, 374 (9th Cir. 2003) (reversing dismissal of plaintiff's antitrust claims when "discontinuation of the only competing product on the market [left consumers with no] viable choice

between market alternatives") (internal citation omitted)); Free Freehand Corp. v. Adobe Sys., 852 F. Supp. 2d 1171, 1182 (N.D. Cal. 2012) ("[I]t is reasonable to infer that Adobe's discontinuation of FreeHand and channeling of FreeHand users to Illustrator made it more difficult for potential competitors of Illustrator . . . to enter the market"); see also Berkey Photo, 603 F.2d at 287 n.39 ("the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera").

The D.C. Circuit case United States v. Microsoft lays out a useful framework for determining whether Defendants have engaged in anticompetitive conduct. 253 F.3d at 58. The plaintiff must demonstrate that the defendant's conduct had an anticompetitive effect. Id. If the plaintiff establishes an anticompetitive effect, then the monopolist may proffer a procompetitive justification for its conduct - "a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." Id. at 58-59. If the monopolist succeeds, then the plaintiff must rebut that justification or

demonstrate that the anticompetitive harm of the conduct outweighs its procompetitive effect. Id. at 59.

The Microsoft case has been widely cited by courts in this circuit, and its framework is frequently employed. See e.g., Meredith Corp. v. Sesac, LLC, 1 F. Supp. 3d 180, 222 (S.D.N.Y. 2014) (citing Microsoft, 253 F.3d at 59, for the proposition that "the determination of § 2 liability calls for a weighing of the exclusionary conduct against any 'valid business reasons' for it."); IHS Dialysis v. Davita, Inc., 2013 U.S. Dist. LEXIS 47532, *24 (S.D.N.Y. Mar. 31, 2013) (citing Microsoft, 253 F.3d at 58 for the proposition "[w]hether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern: the means of illicit exclusion, like the means of legitimate competition, are myriad."); In re Fresh Del Monte Pineapples Antitrust Litig., 2009 U.S. Dist. LEXIS 97289, *21, 55, 69 (S.D.N.Y. Sept. 30, 2009) (utilizing the Microsoft test to determine a § 2 violation). This framework has also more recently been applied in another forced switch antitrust decision, In Re Suboxone Antitrust Litigation, MDL No. 2445 (E.D. Pa. Dec. 3, 2014).

As explained below, anticompetitive effect is adequately demonstrated under the Microsoft framework and Defendants' procompetitive justifications are either not plausible or outweighed by the anticipated anticompetitive effects of the limited distribution strategy.

1. The State Demonstrated Anticompetitive Effect

The State demonstrated a substantial risk that Defendants' limited distribution strategy would harm competition in the memantine market, as found above. See generally FOF § VI. Both regulators and commentators recognize the substantial anticompetitive effect that circumvention of state substation laws can have. See Brief for Federal Trade Commission as Amicus Curiae at 9, Mylan Pharms., Inc., v. Warner Chilcott Pub. Ltd. Co., No. 2:12-CV-03824-PD (E.D. Pa. Dec. 13, 2012) (PX4) ("As a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears."); Brief for Intellectual Prop. & Antitrust Law Professors as Amici Curiae at 14, Mylan (PX5) ("Under Hatch-Waxman and state substitution laws, generics can only compete cost-effectively through substitution on the new or old branded drug version."); cf. FTC v. Actavis, 133 S.Ct. 2223, 2228 (2013) ("The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speed[s] the

introduction of low-cost generic drugs to market . . . thereby furthering drug competition.") (internal quotations and citations omitted).

Defendants undertook to achieve significantly higher levels of conversion from IR to XR precisely by reducing generic competition, putting in place a limited distribution strategy to serve as an "obstacle" to generic switching, thwarting state substitution laws. The result of the forced switch, as found above, is inflation of XR's share of the memantine market. FOF ¶¶ 134, 137. Most patients are effectively denied access to IR for the six month prior to generic entry.

That the limited distribution does not ban all competition does not demonstrate absence of exclusionary behavior. Exclusionary behavior need not result in "total foreclosure" of competition, but rather is found where "the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." Dentsply, 399 F.3d at 191; LePage's Inc. v. 3M, 324 F.3d 141, 159 (3d Cir. 2003); Microsoft, 253 F.3d at 69; In re Fresh Del Monte Pineapples Antitrust Litig., 04-MD-1628, 2009 WL 3241401, at *16 (S.D.N.Y. Sept. 30, 2009) aff'd sub nom. Am. Banana Co. v. J. Bonafede

Co., 407 F. App'x 520 (2d Cir. 2010). "Where a course of action is ambiguous, 'consideration of intent may play an important role in divining the actual nature and effect of the alleged anticompetitive conduct.'" Berkey Photo, 603 F.2d at 288 quoting United States v. United States Gypsum Co., 438 U.S. 422, 436 n.13 (1978).

The State has met its burden under the first prong of Microsoft.

2. Defendants' Procompetitive Justifications Are Pretextual

In evaluating a monopolization claim, the trier of fact must distinguish "between conduct that defeats a competitor because of efficiency and consumer satisfaction, and conduct that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." Trans Sport, Inc. v. Starter Sportswear, Inc., 964 F.2d 186, 188-89 (2d Cir. 1992) (internal quotations and citations omitted); see also Microsoft, 253 F.3d at 59, 65.

The Supreme Court has held that where consumer choices are made as a result of "forcing" customers to purchase a product, then that is not competition on the merits. Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 27 (1984) (condemning tying as anticompetitive where it "restrain[s] competition on the merits by forcing purchases that would not otherwise be made"). Where "the conduct has no rational business purpose other than its adverse effects on competitors, an inference that it is exclusionary is supported." Stearns Airport Equip. Co. v. FMC Corp., 170 F.3d 518, 522 (5th Cir. 1999).

Saunders stated, contemporaneously with the adoption of the hard switch by Forest, that the purpose of the switch was anticompetitive: to put barriers obstacles in the path of producers of generic memantine and thereby protect Namenda's revenues from a precipitous decline following generic entry. FOF ¶ 116. He further stated: "if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing [prescriptions]. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it

can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again go into to a slow decline versus a complete cliff."). FOF ¶ 116.

Saunders's motivation for the hard switch, expressed at the hearing, that his team could better "focus" on XR and FDC if IR was no longer sold by Defendants, was not as specific, or as persuasive, as his earlier representations to shareholders, quoted above. Compare FOF ¶ 78 with ¶ 116; see also FOF ¶ 122.

As found above, Defendants' and Defendants' experts' rationalizations for the hard switch strategy are not only later-in-time but also not as persuasive. The only quantified savings from the limited distribution are roughly [redacted] of the loss of IR revenue within the first six months. FOF ¶ 119. Defendants did not quantify the remaining pro-competitive justifications identified in conjunction with this case. FOF ¶¶ 116, 120. Nor did Saunders elaborate on how the hard switch strategy would allow for greater focus. FOF ¶¶ 116, 120. There is no indication that these ancillary benefits were the basis for Defendants' hard switch strategy. FOF ¶ 121.

Finally, by contending at the hearing that a preliminary injunction against the forced switch would require significant changes to Defendants' operations as a result of the potential loss of [redacted] in sales, Defendants have essentially conceded that it is this expectation of [redacted] increased sales of Namenda XR that is driving their business decision to engage in the forced switch. No other non-pretexual pro-competitive purpose has been established, either at the hearing or by any contemporary Forest analysis.

3. Any Procompetitive Justifications Are Outweighed by the Anticompetitive Impact of the Conduct

To avoid liability, Defendant may offer legitimate business justifications for their exclusionary conduct that outweigh the anticompetitive effects. Microsoft, 253 F.3d at 59; Xerox, 511 F. Supp. 2d at 389. Since these legitimate business justifications must outweigh the anticompetitive effect of the conduct to avoid liability, proffering a minor, immaterial efficiency justification for conduct, the principal purpose and effect of which is to harm competition, will not render such conduct lawful. Microsoft, 253 F.3d at 58-59, 64-66; Xerox, 511 F. Supp. 2d at 388-89; Abbott Labs., 432 F. Supp. 2d at 422. Rather, in such cases, the procompetitive benefits

of the business justification must outweigh the anticompetitive effects.

As discussed above, Defendants have not identified how the limited distribution efficiencies would outweigh [redacted]. The savings from the limited distribution are dwarfed by the loss of IR revenue within the first six months. FOF ¶ 119. The remaining justifications were not quantified. FOF ¶¶ 119-120. More to the point, these cost savings are dwarfed by the considerable anticompetitive harm: both to patients, who will pay [redacted] in higher co-payments or have to switch medications twice, and to third party payors, who will pay more than [redacted]. FOF ¶ 161.

On the basis of these factual findings, Defendants' justifications are outweighed by the anticompetitive effects of the limited distribution. Therefore, there is a serious question as to whether Defendants' limited distribution strategy constitutes competitive conduct.

D. Sherman Act Section 1 Claim

To establish a claim under Section 1 of the Sherman Act, the State must demonstrate: (a) concerted action between Defendants and Foundation Care; (b) resulting in an unreasonable restraint of trade affecting the United States. See Tops Markets, 142 F.3d at 95-96; 15 U.S.C. § 1 ("Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal"); see also Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 885 (2007) (noting that Section 1 is properly construed to bar only unreasonable restraints, not all restrains).

Concerted action within the meaning of Section 1 exists when an agreement between "separate economic actors pursuing separate economic interests . . . deprives the marketplace of independent centers of decisionmaking." Am. Needle, Inc. v. Nat'l Football League, 560 U.S. 183, 195 (2010) (internal quotations and citations omitted). Foundation Care and Defendants are separate economic actors, occupying differing roles in the memantine supply chain: under the hard switch strategy, Defendants remain the sole supplier, or "vendor," and Foundation Care becomes the sole distributor, termed the "independent contractor." FOF ¶ 104. This is sufficient to

establish concerted action. See Anderson News, LLC v. Am. Media, Inc., 680 F.3d 162, 182 (2d Cir. 2012).

Allegations of restraints that are not per se unlawful are analyzed under the rule of reason test, where "the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition." Leegin, 551 U.S. at 885 (2007) (internal citations and quotations omitted). "When applying the rule of reason, courts weigh all of the circumstances surrounding the challenged acts to determine whether the alleged restraint is unreasonable, taking into account factors such as specific information about the relevant business, the restraint's history, nature, and effect, and whether the businesses involved have market power." Gatt Commc'ns, Inc. v. PMC Associates, L.L.C., 711 F.3d 68, 75 (2d Cir. 2013) (internal quotations omitted) citing Leegin, 551 U.S. at 885).

The Section 2 analysis above satisfies the unreasonable restrain prong. Defendants have monopoly power in the memantine market. See generally FOF § IV. The hard switch strategy will likely have an anticompetitive effect on that

market, denying current memantine patients access the IR tablets and driving up the average price of memantine following generic entry. See generally FOF § VI. In sum, the hard switch strategy constitutes an unreasonable restrain on trade without a pro-competitive justification, as discussed above.

The cases Defendants cite in opposition to this claim do not alter this conclusion. While it is true that manufacturers generally have control over distribution, E & L Consulting, Ltd. v. Doman Indus. Ltd., 472 F.3d 23, 30 (2d Cir. 2006), they are not permitted to exert that control in a manner that violates the antitrust laws. See Leegin, 551 U.S. at 892 (discussing the illegality of vertical restraints).

In E & L Consulting, the Second Circuit affirmed dismissal of a Section 1 claim for failure to plead that the concerted action would yield an adverse effect on the market. 472 F.3d at 31. The facts in that case established that the defendant-monopolist would continue to enjoy monopoly power with or without the agreement in question. Id. at 29 (the monopolist held 95% of the market). Since the defendant in E & L Consulting did not need the agreement to further its monopoly, the Second Circuit concluded that the agreement was not a proper

basis for Section 1 liability. Id. at 30. By contrast, Defendants in this case face potential competition from numerous generic manufacturers in summer of 2015, and are relying on the MSA to maintain their market power. This is also not a case where the vertical agreement is made for a pro-competitive reason. Compare the anticompetitive effect in this case with that in Cont'l T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36 (1977) ("[v]ertical restrictions promote interbrand competition by allowing the manufacturer to achieve certain efficiencies in the distribution of his products").

As with the Section 2 claims, the State has demonstrated a substantial question exists as to the legality of the MSA as governed by Section 1 of the Sherman Act.

E. State Law Violations by Defendants

The Donnelly Act makes illegal and void any contract, arrangement, or agreement that restrains competition in any business, or unlawfully interferes with the free exercise of any activity in the conduct of any business, and is generally construed in accordance with the Sherman Act. See N.Y. Gen.

Bus. Law § 340; Anheuser-Busch, Inc. v. Abrams, 71 N.Y.2d 327, 334 (N.Y. 1988).

"A plaintiff alleging a claim under the Donnelly Act must identify the relevant product market, allege a conspiracy between two or more entities, and allege that the economic impact of that conspiracy was to restrain trade in the relevant market." Thome v. Alexander & Louisa Calder Found., 890 N.Y.S.2d 16, 32 (App. Div. 2009); see also, Benjamin of Forest Hills Realty, Inc. v. Austin Sheppard Realty, Inc., 823 N.Y.S.2d 79 (App. Div. 2006); Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp., 224 F. Supp. 2d 657, 678 (S.D.N.Y. 2002).

The Donnelly Act analysis tracks the Section 1 of the Sherman Act claim, as analyzed above. As with the Section 1 claim, the State has met its burden of demonstrating a substantial question going to the merits of this claim.

Under Section 63(12), the New York State Attorney General may sue defendants for violations of state or federal law, including Sherman Act or Donnelly Act violations, affecting more than one person within New York State. N.Y. Exec. L. §

63(12); State v. Feldman, 210 F. Supp. 2d 294, 300 (S.D.N.Y. 2002) (antitrust violations are predicate offenses); State v. Stevens, 497 N.Y.S.2d 812, 813 (N.Y. Sup. Ct. 1985); People v. Wilco Energy Corp., 728 N.Y.S.2d 471, 471 (2d Dep't 2001) (the Attorney General can show repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person to satisfy the "repetition" requirement under the law).

As discussed above, the State has established a substantial question on the merits of its Sherman and Donnelly Act antitrust claims, and therefore also satisfied adequately established these claims as well.

IX. A Preliminary Injunction Is Appropriate

Upon the establishment of serious questions of antitrust violations as concluded above, the standard questions for preliminary injunction relief remain and are concluded in favor of the State. The irreparable injury has been established, the balance of hardships tips markedly in the favor of the State, and the public interest is best served by preliminary relief maintaining the status quo.

Since the introduction of Namenda XR in 2013, Forest has successfully marketed and sold both XR and IR products. FOF ¶ 53. Namenda IR has been in the market since 2004 and its yearly sales have exceeded $1.5 billion, as found above. FOF ¶ 44. The present Forest sales program is consistent with an accepted industry practice of a soft switch when a new product is introduced, a practice that maintains consumer choice before and after generic entry into the market. FOF ¶ 36. To maintain the status quo is appropriate relief under the circumstances here presented.

A. Irreparable Harm Has Been Established

Although the State has maintained otherwise, see Pl.'s Mem. in Supp't 40, it is not entitled to a presumption of irreparable harm. See 15 U.S.C. § 26 (authorizing injunction "when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity . . . and a showing that the danger of irreparable loss or damage is immediate"); Salinger v. Colting, 607 F.3d 68, 78 n.7 (2d Cir. 2010) (noting that eBay Inc. v. MercExchange, LLC, 547 U.S. 388, (2006), eliminated all

presumptions of irreparable harm absent contrary explicit congressional intent); see also Weinberger v. Romero-Barcelo, 456 U.S. 305, 313 (1982) (statute should not be read lightly to replace traditional equity test). Therefore, the State "must demonstrate that absent a preliminary injunction [it] will suffer an injury that is neither remote nor speculative, but actual and imminent, and one that cannot be remedied if a court waits until the end of trial to resolve the harm." Grand River Enter. Six Nations, Ltd. v. Pryor, 481 F.3d 60, 66 (2d Cir. 2007) (internal quotations and citations omitted). Consequently, the State must show that there is a "substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." Brenntag Int'l Chemicals, Inc. v. Bank of India, 175 F.3d 245, 249 (2d Cir. 1999).

The facts found above established that that patients, caregivers, and physicians will be constrained in obtaining Namenda IR in the absence of a preliminary injunction. FOF ¶ 112. Permanent damage to competition in the memantine market can also result from Defendants' planned hard switch strategy. See generally FOF § VI.A.

In addition, in the absence of a preliminary injunction and in the accomplishment of the Defendants' hard switch, consumers will pay almost $300 million more for a memantine drug than if the present sales patter is maintained. Although this is a projected financial loss to Alzheimer's patients, it can be avoided by maintaining the status quo. See Bon-Ton Stores v. May Dep't Stores Co., 881 F. Supp. 860, 866 (W.D.N.Y. 1994) ("With respect to irreparable harm, doubts as to whether an injunction sought is necessary . . . should be resolved in favor of granting the injunction.") (internal quotations and citations omitted).

B. The Balance of Hardships Tips in Favor of the State

In determining whether to grant a preliminary injunction, courts consider the balance of harms between the movant and the party subject to the injunction. See Amoco Prod. Co. v. Vill. of Gambell, 480 U.S. 531, 542 (1987); Random House, Inc. v. Rosetta Books LLC, 283 F.3d 490, 492 (2d Cir. 2002).

The facts found above demonstrate that the hard switch will injure competition and consumers. See generally FOF § VI. Conversely, the Defendants have not demonstrated any harm

resulting from their continuing the same IR distribution strategy they have been using since 2004. FOF ¶ 38. And Defendants have failed to quantify any material costs that would result from an injunction. FOF ¶¶ 116, 120. No evidence has been submitted that continuing to supply the market with Namenda IR, an activity they have been doing by choice for over a decade, constitutes a hardship. To the contrary, the evidence suggests that continuing to sell IR will be a net benefit to Defendants, [redacted] FOF ¶ 118.

Having to compete with other firms in the market is what the antitrust laws require, not a cognizable harm. Harm is not established by refraining conduct that "seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect." Abbott Labs., 432 F. Supp. 2d at 422. As found above, Defendants actually risk losing [redacted] in revenues gained through anticompetitive, i.e., illegally, conduct. This is not a cognizable harm.

C. The Public Interest Favors Granting the Injunction

Finally, "[c]ourts of equity may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved.") (internal quotations and citations omitted." United States v. First Nat'l City Bank, 379 U.S. 378, 383 (1965); accord Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 424 (2d Cir. 2004) quoting Standard & Poor's Corp. v. Commodity Exch., Inc., 683 F.2d 704, 711 (2d Cir. 1982).

Here, the State seeks to enforce laws on behalf of the public. FOF ¶ 1. Courts presume that government action taken in furtherance of a regulatory or statutory scheme is in the public interest. See, e.g., Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 424 (2d Cir. 2004). Enforcing the antitrust laws serves the public interest in a competitive marketplace, here the memantine market. See United States v. Siemens Corp., 621 F.2d 499, 506 (2d Cir. 1980).

Additionally, a preliminary injunction will protect the public interest by safeguarding the fundamental compromise envisioned by the Hatch-Waxman Act, which sought to reconcile the sometimes conflicting public policy goals of making affordable generic drugs available to consumers and protecting

pharmaceutical companies' incentives to innovate. FOF § II.E. Defendants have accepted a five-year extension to their patent rights, took advantage of pediatric exclusivity, and used Hatch-Waxman's mechanism for delaying generic entry by suing would-be generic competitors, thus delaying their approval. FOF ¶ 38. The hard switch violates the spirit of the Hatch-Waxman Act and the public policy underlying it.

Defendants have contended that allowing them to engage in the hard switch will allow increased innovation in the long term, as greater financial resources are made available to Defendants. Defs.' Mem. in Opp'n 23. However, optimizing the incentives for innovation requires that the legal system reward pharmaceutical companies for truly innovative conduct that benefits consumers, by means of better drugs that physicians and patients are willing to switch to voluntarily. Providing financial rewards for anticompetitive conduct is not in the public interest.

Conclusion

Based upon the finding of fact conclusions of law set forth above, a preliminary injunction will issue. The State will submit a proposed preliminary injunction by 5:00 PM on December 12, 2014, and a hearing will be held in Courtroom 23B on December 15, 2014 at noon.

It is so ordered.

New York, NY
December 11, 2014

ROBERT W. SWEET
U.S.D.J.

EXHIBIT 252

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION	Civil Action No. 1:15-cv-07488-CM

THIS TRANSCRIPT IS HIGHLY CONFIDENTIAL

VIDEOTAPED DEPOSITION OF ERIC AGOVINO

Westlake Village, California

Tuesday, September 12, 2017

Volume I

Reported by:

KATHLEEN E. BARNEY

CSR No. 5698

Job No. 2672438

PAGES 1 - 163

Page 42

A I don't recall the exact date. 09:47:49
Q Was he the CEO when you arrived? 09:47:52
A Yes. 09:47:54
Q And who was Dr. Huchmann? 09:47:54
A Huchmann. Dr. Huchmann was the chairman of 09:47:59
Merz. 09:48:04
Q So was this a Paragraph IV certification or 09:48:05
notice letter that was sent to Forest and Merz by 09:48:11
Mylan with respect to its Paragraph IV ANDA with 09:48:18
respect to Namenda? 09:48:22
A That's what it looks like. 09:48:23
Q Okay. If you turn to the second page, it 09:48:24
says -- there's the next-to-the-last paragraph: 09:48:30
[redacted]
Do you see that, sir? 09:48:42
A Yes. 09:48:43
Q And then the following pages to the end of 09:48:43
the document -- in fact, the first page on Bates 09:48:45
ending in 426 says: 09:48:52
[redacted]

Page 43

[redacted]
Do you see that, sir? 09:49:03
A Yes. 09:49:04
Q Okay. Does that -- does that lead you to 09:49:04
believe that this was the -- that this was submitted 09:49:12
to Forest with respect to Mylan's Paragraph IV ANDA 09:49:17
certification? 09:49:22
A Can you rephrase that? 09:49:23
Q Would it be reasonable to conclude that 09:49:28
Silber Exhibit 6 was Mylan's Paragraph IV notice of 09:49:32
certification letter and detailed statement 09:49:40
submitted with respect to its Paragraph IV 09:49:43
application to market a generic version of Namenda? 09:49:46
MR. TOTO: Objection. Asked and answered. 09:49:50
THE WITNESS: I don't know if this is the 09:49:51
exact letter. It says on it that it's a 09:49:54
Paragraph IV notice, but I don't know that this is 09:49:57
the one that they actually sent. 09:49:59
BY MR. OPPER: 09:50:02
Q Do you have any reason to doubt that this was 09:50:02
received by Forest and is what it represents to be? 09:50:04
A I have no reason to doubt that. 09:50:08
Q Did each of the other 15 generic companies 09:50:10
that filed Paragraph IV ANDAs with respect to 09:50:25
Namenda submit a similar notice and detailed 09:50:31

Page 44

statement of the factual basis for the claims 09:50:35
regarding the -- why their product did not infringe 09:50:38
the '703 patent? 09:50:43
MR. TOTO: Objection to form. Vague and 09:50:44
ambiguous. Overbroad. Compound. 09:50:47
THE WITNESS: So my answer is they sent us a 09:50:48
notice letter. I don't know how similar their 09:50:51
allegations were. 09:50:54
BY MR. OPPER: 09:51:04
Q Mr. Agovino, if you could go back to Mears 8, 09:51:04
and I'll ask you to look at the second page. 09:51:07
Do you recall which of these companies 09:51:13
identified were first filers? 09:51:18
A I don't know which ones were first filers. I 09:51:21
know that there were a few that were definitely not 09:51:42
first filers. 09:51:45
Q Who were those that were not first filers? 09:51:46
A Apotex, Torrent, and I don't -- that's as far 09:51:48
as my memory goes. 09:51:59
Q Do you recall whether Mylan was a first 09:52:00
filer? 09:52:11
A I believe they were. 09:52:11
Q And do you recall whether Orchid was a first 09:52:16
filer? 09:52:20
A I don't recall exactly. 09:52:21

Page 45

Q Were there more than five first filers with 09:52:26
respect to Namenda? 09:52:30
A I think that's fair. 09:52:32
Q Were there more than ten? 09:52:33
A I don't know that. 09:52:36
Q Okay. So your recollection is that it was 09:52:38
more than five, but you don't know how many? 09:52:42
A Correct. 09:52:44
Q I'm not sure if I asked you, what is the 09:52:45
benefit or significance to a generic company of 09:52:53
being a first filer? 09:52:56
A If they prevail in the litigation, they would 09:52:58
be eligible to receive 180 days of marketing 09:53:03
exclusivity. 09:53:08
Q What happens in circumstances where there are 09:53:08
more than one first filers? 09:53:11
A So if they all file on the same day, they 09:53:13
potentially share that 180-day exclusivity period. 09:53:16
Q Do you know whether the entry by one generic 09:53:20
company would trigger the 180-day period for the 09:53:24
other first filers? 09:53:27
A That, I don't -- I'd have to think about that 09:53:28
one. 09:53:33
Q So would it be fair to say that based on your 09:53:33
recollection, there were at least five first filing 09:53:36

Page 54

well? 10:04:24
A Yes. 10:04:24
Q And with respect to Orchid and Mylan, you 10:04:25
were involved in those negotiations? 10:04:28
MR. TOTO: Settlement negotiations? 10:04:31
MR. OPPER: Yes. 10:04:33
BY MR. OPPER: 10:04:33
Q I'm sorry. The settlement negotiations. 10:04:34
A Charles and I were involved with the 10:04:36
settlement of the patent litigation for Mylan and 10:04:39
Orchid. 10:04:44
Q Okay. Did -- with respect to Mylan, did -- 10:04:44
between the two of you, did either of you have 10:04:46
principal authority -- let me withdraw that. 10:04:49
With respect to Mylan, did either you or 10:04:51
Mr. Ryan have primary responsibility for negotiating 10:04:55
the settlement agreement? 10:04:59
A Charles was my boss. We worked together, but 10:05:00
he was -- I reported to him. 10:05:04
Q To the extent there were negotiations, actual 10:05:08
negotiations with the generic manufacturer, let's 10:05:12
say on the telephone, would both you and Charles 10:05:15
Ryan have been involved? 10:05:18
MR. TOTO: Object to form. 10:05:19
You may answer. 10:05:21

Page 55

THE WITNESS: In general, we were on the 10:05:21
phone at the same time. 10:05:23
BY MR. OPPER: 10:05:26
[redacted]
MR. TOTO: Object to form. 10:05:37
[redacted]
BY MR. OPPER: 10:05:42
[redacted]
BY MR. OPPER:
[redacted]

Page 56

MR. TOTO: I'm going to object that it's 10:06:34
overbroad and compound. 10:06:36
You may answer. 10:06:37
[redacted]
BY MR. OPPER: 10:06:40
[redacted]
But if you're capable of answering that 10:07:12
question, go ahead. 10:07:15
THE WITNESS: Sorry. Can you repeat that? 10:07:17
BY MR. OPPER:
Q Do you recall whether Forest ever sent a 10:07:19
draft settlement agreement to a generic company that 10:07:22
was unsolicited by that generic company? 10:07:26
A The question was whether it was unsolicited? 10:07:30
Q Yes. 10:07:33
MR. TOTO: Object to form. Vague and 10:07:33
ambiguous. 10:07:35
THE WITNESS: I can't recall. 10:07:35
////

Page 57

BY MR. OPPER: 10:07:36
Q Do you recall who was the first generic 10:07:41
manufacturer to enter into a settlement agreement 10:07:45
with Forest? 10:07:48
A So if we're excluding Ranbaxy, Synthon, Barr 10:07:49
and Genpharm, I believe the first one was Amneal. 10:08:05
Q All right. Let me -- I'd like to introduce 10:08:24
as Agovino 1 a document Bates stamped 10:08:31
FRX-AT-00000218 through 252. 10:08:48
A Okay.
(Exhibit 1 was marked for identification by
the court reporter and is attached hereto.)
BY MR. OPPER: 10:09:52
Q Do you recognize what has been marked as 10:09:52
Agovino 1? 10:09:54
A Yes. 10:09:56
Q And what do you recognize it to be? 10:09:56
A A settlement agreement between Forest, Forest 10:10:00
Holdings, Merz, and various Amneal entities. 10:10:04
Q And this is the Amneal settlement agreement 10:10:08
that you were referring to? 10:10:12
A Yes. 10:10:13
[redacted]
Q Now, would it be fair to say this was the 10:10:21

Q And I believe that you suggested that Forest did get a patent term extension with respect to the '703 patent? 10:20:25 10:20:33 10:20:37

A To be clear, Merz owned the patent. They were the ones who obtained the patent extension. 10:20:38 10:20:41

Q But Merz did receive a patent extension, patent term extension? 10:20:45 10:20:47

A The '703 patent was awarded a patent term extension. 10:20:48 10:20:52

Q Do you recall what the expiration date of the patent term extension was? 10:20:53 10:20:55

A The PTO granted patent term extension of a full five years. My recollection, sitting here today, is that it was April of 2015. 10:20:57 10:21:01 10:21:05

Q If I said April 11, 2015 -- 10:21:08

A Sounds right. 10:21:14

Q So prior to the patent term extension, the patent would have expired in April 11, 2010; is that correct? 10:21:15 10:21:19

A Sounds right. 10:21:27

MR. TOTO: Can you keep going for a little while or break? 10:21:33 10:21:35

THE WITNESS: I'm fine. 10:21:37

MR. TOTO: Maybe we'll go for a little longer and take a break. It's been a while, but we'll keep 10:21:38 10:21:41

going right now. 10:21:45

BY MR. OPPER: 10:21:45

Q Okay. The launch date in the Amneal agreement says: 10:21:49 10:21:52

"Launch date shall mean the later of, Subsection 3, three calendar months prior to the expiration of the '703, including any extensions." 10:21:53 10:21:55 10:21:59 10:22:00

And I believe you testified that Forest -- or Merz did get an extension; is that correct? 10:22:03 10:22:07

A I did testify to that, yes. 10:22:09

Q And so the date as reflected by the patent term extension would be the launch date for purposes of this section? 10:22:11 10:22:16 10:22:19

MR. TOTO: Object to form. 10:22:21

THE WITNESS: Can you repeat that? 10:22:23

MR. TOTO: The document speaks for itself. 10:22:25

BY MR. OPPER: 10:22:25

Q With respect to the three calendar months prior to the expiration -- let me just back up a bit. 10:22:27 10:22:29 10:22:33

The launch date, that provides the date for which Amneal would be able to enter the market with a generic version of Namenda; is that correct? 10:22:34 10:22:38 10:22:41

MR. TOTO: Object to form. Vague and 10:22:43

ambiguous. Document speaks for itself. 10:22:46

THE WITNESS: So the launch date is -- and this is a long agreement. The launch date is mentioned a few times, but I would just qualify what you said with the fact that there were pre-booking activities as well that were prior to the launch date that we granted Amneal. 10:22:47 10:22:52 10:22:57 10:23:02 10:23:05 10:23:08

BY MR. OPPER: 10:23:10

Q Okay. But would it be fair to say the launch date with respect to this agreement is defined in paragraph 1.14 of the settlement agreement and license? 10:23:12 10:23:14 10:23:16 10:23:21

A There is a definition of launch date in Section 1.14. 10:23:21 10:23:25

Q So given the fact that Merz obtained a patent term extension until April 2015, the three calendar months prior, as provided in this term, would be with respect to that 4/11/15 date; is that correct? 10:23:26 10:23:39 10:23:45 10:23:48

MR. TOTO: Object to form. Document speaks for itself. 10:23:54 10:23:55

THE WITNESS: Yes. There's also pediatric exclusivity mentioned here. I'll just note that. 10:24:02 10:24:05

BY MR. OPPER: 10:24:08

Q Putting aside pediatric exclusivity for now. 10:24:09

A Putting that aside, I would agree that it 10:24:13

would be three months prior to the extended date. 10:24:15

Q What is pediatric exclusivity? 10:24:18

A Pediatric exclusivity is an award that is granted for companies to conduct studies in patient populations that are not well served. It's an incentive for them to conduct those studies. 10:24:22 10:24:34 10:24:40 10:24:44

Q Did Forest receive pediatric exclusivity with respect to Namenda? 10:24:46 10:24:51

A So pediatric exclusivity was granted for memantine, which is the molecule. 10:24:54 10:25:02

Q So given the fact that Merz received a patent term extension and Forest received pediatric exclusivity, what would the date be as contemplated by Subsection A of Section 1.14? 10:25:04 10:25:07 10:25:11 10:25:16

MR. TOTO: Object to form. 10:25:22

THE WITNESS: If you take three months off the patent, including extensions and/or exclusivity, it would be July of 2015. 10:25:23 10:25:31 10:25:36

BY MR. OPPER: 10:25:38

Q Or July 11 of -- 10:25:38

A July 11, around that time. 10:25:40

Q I believe that is the date, but --

A But, again, the other thing I'll note is it says the date that Amneal obtains final approval. So if they didn't get final approval by then, then 10:25:44 10:25:46 10:25:49

Page 74

A I don't recall the specific language, but they did not have three months early entry.
Q So they -- Apotex was not licensed to enter the market prior to patent expiration?
A They -- they did not have that three-month prior language, that's right.
Q Other than Apotex, did all the other generic manufacturers with which Forest settled have the word-for-word identical launch date?
MR. TOTO: Same objection.
THE WITNESS: So just to be clear, we're not talking about any of the ones on that list that are in the other categories?
BY MR. OPPER:
Q That was Mears 8, yes. We're talking about the --
A Just the ten?
Q The ten that settled and Mylan and Orchid. 12.
A Got it. Okay. So the answer is no.
Q Okay. Which generic companies did not get the identical launch date?
MR. TOTO: Object to form.
THE WITNESS: I don't know if -- sitting here today, if the language was the same for each

Page 75

company. I've already identified Apotex. I believe Torrent also did not have three months early entry. But, again, I don't know for the rest if the language is exactly the same.
BY MR. OPPER:
Q Well, whether the generic manufacturer got the same launch date, did that depend upon whether it was a first filer?
A Yes.
Q Okay. So would it be fair to say that all of the generic companies that were first filers got a word-for-word identical launch date in their settlement agreements?
MR. TOTO: Objection. Documents speak for themselves.
THE WITNESS: I don't know if it's a word-for-word identical.
BY MR. OPPER:
Q But in substance would you say they were identical?
MR. TOTO: Same objection.
THE WITNESS: I think they all had three months early entry. That's the -- that's what we announced -- Forest announced in their press release.

Page 76

BY MR. OPPER:
[redacted]
MR. TOTO: I caution you not to reveal the substance of any privileged communications or privileged legal analysis, which may mean you can't answer the question. But I defer to you.
BY MR. OPPER:
Q Well, let me withdraw that question because I'm not trying to be tricky. I just want to know if you're going to assert privilege objections.
[redacted]
MR. TOTO: So that is a yes or no question.
[redacted]
BY MR. OPPER:
Q And what was the advice or position conveyed by Forest's counsel?
MR. TOTO: I'll object and instruct you not to answer.

Page 77

BY MR. OPPER:
Q Are you going to follow your attorney's instructions?
A Yes.
[redacted]
MR. TOTO: Objection. Document speaks for itself.
You may answer.
[redacted]
BY MR. OPPER:
[redacted]

Page 78

[redacted]
MR. TOTO: You may answer.
[redacted]
BY MR. OPPER:
[redacted]
MR. TOTO: Objection. Documents speak for themselves.
[redacted]
BY MR. OPPER:
[redacted]
MR. TOTO: And, again, I caution you not to

Page 79

get into any privileged communications.
[redacted]
BY MR. OPPER:
[redacted]
MR. TOTO: Object to form.
[redacted].
BY MR. OPPER:
[redacted]
MR. TOTO: Objection. Compound. Overbroad.
[redacted]
BY MR. OPPER:
[redacted]

Page 80

[redacted]
MR. TOTO: Object to form. Vague and ambiguous. What provision are we even talking about? 8 now?
[redacted]

Page 81

[redacted]
BY MR. OPPER:
[redacted]
MR. TOTO: Object to form. Lacks foundation.
[redacted]
MR. OPPER: This might be a good time for a break.
MR. TOTO: Sure.
THE VIDEOGRAPHER: Off the record. 10:41.
(Recess.)
THE VIDEOGRAPHER: The time is 10:54. We are back on the record.
BY MR. OPPER:
[redacted]

Page 138

amendment. I was part of the settlement agreement and the license agreement, and we had different teams negotiating each of these.

BY MR. OPPER:

[redacted]

MR. TOTO: Objection. Lacks foundation. Calls for speculation.

[redacted]

BY MR. OPPER:

[redacted]

MR. TOTO: Objection. Calls for speculation.

[redacted]

Page 139

BY MR. OPPER:

[redacted]

[redacted]: Objection. Document speaks for itself.

THE WITNESS: Can you repeat that? I'm sorry.

MR. OPPER: Could you read back the question, please.

(Record read.)

[redacted]

BY MR. OPPER:

[redacted]

MR. TOTO: Objection. Asked and answered. Calls for speculation.

[redacted]

Page 140

BY MR. OPPER:

[redacted]

MR. TOTO: Objection. Lacks foundation. Calls for speculation. Misstates prior testimony.

[redacted]

BY MR. OPPER:

[redacted]

MR. TOTO: Objection. Asked and answered.

[redacted]

BY MR. OPPER:

[redacted]

Page 141

[redacted]

MR. TOTO: Hold on one second.

THE WITNESS: I was going to ask to repeat that question. I got lost.

MR. OPPER: Repeat it, please.

(Record read.)

[redacted]

MR. OPPER: Okay. If we could have a break. I think I have probably another half an hour.

MR. TOTO: Okay.

THE VIDEOGRAPHER: Off the record. 12:45.

(Recess.)

THE VIDEOGRAPHER: We are back on the record. The time is 12:58.

BY MR. OPPER:

Q Mr. Agovino, was Dr. Reddy's one of the generic manufacturers that filed an ANDA with the Paragraph IV certification regarding Namenda?

A Yes. Dr. Reddy's filed a Paragraph IV.

Q Was Dr. Reddy's one of the first filers?

A I believe they were.

Q Were you involved in negotiating the patent litigation settlement with Dr. Reddy's?

A Yes.

Page 158

BY MR. OPPER: 01:29:51

[redacted]

01:30:10

[redacted]

Page 159

[redacted]

MR. OPPER: Thank you. I have no further questions. 01:31:38 01:31:40

MR. TOTO: Okay. I have a few questions. 01:31:40

EXAMINATION

BY MR. TOTO:

[redacted]

MR. OPPER: Objection to form. 01:32:09

[redacted]

BY MR. TOTO: 01:32:16

[redacted]

Page 160

Do you recall that testimony? 01:32:28

A Yes. 01:32:29

[redacted]

MR. OPPER: Objection as to form. 01:32:38

[redacted]

BY MR. TOTO: 01:32:40

Q Now, under the Hatch-Waxman scheme, when there are multiple first filers, such as with respect to Namenda, are all the first filers entitled to enter on the same date, assuming they have approval to do so? 01:32:41 01:32:47 01:32:50 01:32:52 01:32:57

A Yes. 01:32:58

MR. OPPER: Objection as to form. 01:32:59

THE WITNESS: Yes. 01:33:00

BY MR. TOTO: 01:33:00

[redacted]

MR. OPPER: Objection as to form. 01:33:12

[redacted]

BY MR. TOTO: 01:33:18

[redacted]

[redacted]

MR. OPPER: Objection as to form. 01:34:22

[redacted]

MR. TOTO: No further questions. 01:34:25

MR. OPPER: I'm done. 01:34:27

THE VIDEOGRAPHER: This concludes today's testimony given by Eric Agovino. All recorded media will be retained by Veritext Legal Solutions. We're off the record at 1:34. Thank you. 01:34:30 01:34:37 01:34:41 01:34:44

(TIME NOTED: 1:34 p.m.)

EXHIBIT 263

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In Re: Namenda 343 Statement

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State of New York
Office of the Attorney General
120 Broadway, 26th Floor, Antitrust Bureau
New York, New York 10271

August 21, 2014
9:36 a.m.

Witness: Mark Devlin
Reported By: Anthony Giarro

* TRANSCRIPT OF PROCEEDINGS *

DX503

MARK DEVLIN

Q Do you remember what Kevin said to you?

A I believe they were just general discussions about manufacturing process, the burden, general discussions about his visits to Ireland in our manufacturing facility there.

Q Did he say to you that they could not maintain production of both IR and XR?

MR. TOTO: Object to form.

A I don't recall if he specifically said that.

Q Just going back to Exhibit 3.

A Okay.

[redacted]

Q What does it mean to transition patients to Namenda XR?

MR. TOTO: Object to form.

MARK DEVLIN

Q What is your understanding of that language?

A I don't know what Mr. Samoriski exactly meant with his statement.

Q I'm asking for your understanding when you read this.

A My understanding is that to transition patients to Namenda XR requires the physician to make the judgment. That's what they want the patient to be on and to write the prescription for it.

Q And you didn't understand that to mean Forest's transition of patients to XR?

MR. TOTO: Object to form.

A As I said before, my view is Forest does not transition patients. A physician does that.

[redacted]

MARK DEVLIN

[redacted]

MARK DEVLIN

[redacted]

MR. TOTO: Object to form.

[redacted]

consideration.

Q Was that ever adopted?

MR. TOTO: Object to form.

A I don't recall. I don't believe so. But I don't recall specifically.

Q Let's look at the next document, Exhibit 7.

A Okay.

Q Earlier in your testimony, I think you said you couldn't recall whether the managed care companies, your customers said anything about waiting for the introduction of generic IR. Does this refresh your recollection?

MR. TOTO: Object to form.

A That the managed care companies were --

[redacted]

MR. TOTO: Object to form.

I'm not sure it's a question. You may answer if you understand the

question.

A I don't fully understand the question, no.

[redacted]

MR. TOTO: Object to form; assumes facts, lacks foundation. Also, do you intend to show the witness the PowerPoint that's attached that this is a comment about?

MS. HOFFMANN: I don't have the slides.

MR. TOTO: I object to this line of questioning. This is clearly comments of an attached PowerPoint.

You may answer.

[redacted]

[redacted]

Q If Forest discontinued IR, would that limit the loss of XR business to generic IR?

MR. TOTO: Object to form.

You may answer.

A It may; it may not.

Q Did you talk to anyone at Forest about that possibility?

MR. TOTO: Object to form.

A Possibility of losing --

Q Less XR business to generic IR if IR were discontinued.

A I think that came up in some discussions.

Q Discussions with whom?

EXHIBIT 273

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 1:15-cv-07488-CM

- - - - - - - - - - - - - - - - - -
IN RE NAMENDA DIRECT PURCHASER
ANTITRUST LITIGATION
- - - - - - - - - - - - - - - - - -

VIDEO DEPOSITION OF MARTIN R. FARLOW, M.D.

HIGHLY CONFIDENTIAL

The video deposition upon oral examination of MARTIN R. FARLOW, M.D., a witness produced and sworn before me, Judith E. Bellinger, RPR, CRR, CSR No. 94-R-1044, a Notary Public in and for the County of Marion, State of Indiana, taken on behalf of the Plaintiffs at the offices of CONNOR REPORTING, 111 Monument Circle, Suite 4350, Indianapolis, Marion County, Indiana, on the 11th day of November, 2017, commencing at the hour of 8:59 a.m., pursuant to the Federal Rules of Civil Procedure with written notice as to the time and place thereof having been given.

[redacted]

Q Sorry. With which people did you prepare for today's deposition? 09:04:25 09:04:30

A I'm not sure I understand what you're saying. 09:04:33

Q Did you meet with anyone to prepare for today's deposition? 09:04:35 09:04:37

A No. 09:04:37

Q Okay. So I think you mentioned that you reviewed your expert report that you submitted in this case in preparation for today's deposition; is that correct? 09:04:38 09:04:45 09:04:47 09:04:49

A Yes. 09:04:52

Q Okay. And did you review your expert report from the patent litigation for today's deposition? 09:04:52 09:04:56 09:04:59

A Yes. 09:05:01

Q Did you review Dr. Doody's expert report from the Namenda patent litigation? 09:05:01 09:05:06

A Yes. 09:05:11

Q Did you review Dr. Doody's opposition report for the patent litigation? 09:05:11 09:05:14

A I'm not sure. I don't think so. 09:05:21

Q Okay. Did you review Dr. Olney's expert report from the Namenda patent litigation? 09:05:22 09:05:28

A No. 09:05:30

Q Did you review Dr. Doody's deposition transcript from the Namenda patent litigation? 09:05:36 09:05:39

A No. 09:05:42

Q Did you review Dr. Schneider's expert report? 09:05:46

A Yes. 09:05:50

Q Do you know Dr. Schneider? 09:05:52

A Yes. 09:05:54

Q How long have you known him? 09:05:56

A Twenty years. 09:06:02

Q Are you familiar with his work? 09:06:03

A Yes. 09:06:06

Q In what way? 09:06:06

A He is an academic psychiatrist who has been actively involved in investigational trials and clinical research, and I'm engaged in similar activities and have seen him at meetings. 09:06:10 09:06:19 09:06:24 09:06:30

Q Have you co-authored articles with Dr. Schneider? 09:06:38 09:06:40

A Yes. 09:06:41

Q Do you know approximately how many articles you've co-authored with him? 09:06:42 09:06:44

A Not off the top of my head, but I would guess half dozen, 10. 09:06:50 09:06:53

Q Would you say that Dr. Schneider is a prominent expert in the field of Alzheimer's disease? 09:06:57 09:07:02

A Yes. 09:07:04

Q Would you agree that he is well respected in the field of Alzheimer's disease? 09:07:05 09:07:09

A Yes. 09:07:11

Q Would you agree that Dr. Schneider is knowledgeable about Alzheimer's disease? 09:07:13 09:07:15

A Yes. 09:07:18

Q Do you know Dr. Herrmann? 09:07:20

A No. 09:07:23

Q Did you review U.S. patent No. 5061703 in preparing for today's deposition? 09:07:26 09:07:30

A Give me the number again, please. 09:07:35

Q 5061703. 09:07:37

A '703, yes. 09:07:39

Q And if I refer to this patent just as the '703 patent for convenience today, will you understand what I'm referring to? 09:07:41 09:07:44 09:07:47

A Yes. 09:07:48

Q Okay. Do you know what the field of medicinal chemistry includes? 09:07:49 09:07:56

MR. MAJCHRZAK: Objection. Vague. 09:08:02

A I'm not sure what you're asking. It's a broad question; yes, generally, but it's a very broad question. 09:08:06 09:08:11 09:08:14

Q Have you used the term "medicinal chemistry" before? 09:08:14 09:08:18

A I do not routinely use that term, no. 09:08:19

Q Let me ask you: In order to treat or prevent a medical condition, would you agree that a drug must have a therapeutic effect? 09:08:26 09:08:32 09:08:35

A It's almost definitional, but, yes. 09:08:42

Q What do you understand the term "cerebral ischemia" to mean to a person of ordinary skill in the art? 09:08:47 09:08:48 09:08:55

MR. MAJCHRZAK: Objection. 09:08:56

A There is a general meaning now. There are other meanings that have been assigned by the court in the past with regard to this case. Which do you want? 09:08:59 09:09:03 09:09:05 09:09:08

[redacted]

Page 14

[redacted]

Q I would like to go ahead and mark as Exhibit -- 09:09:38
Farlow Exhibit 1, your expert report. Make sure 09:09:44
I've got the right one. From this litigation, 09:09:49
it's dated October 9th, 2017. 09:09:55
(Exhibit 1 was marked for identification.) 09:10:10
Q Do you recognize this document? 09:10:25
A Yes. 09:10:29
Q And would you agree that this is the expert 09:10:30
report that you submitted in this antitrust 09:10:33
litigation? 09:10:36
A Yes. 09:10:41
Q And if you turn to page -- oh, the pages aren't 09:10:46
numbered. The page after 23. Is that your 09:10:55
signature? 09:10:58
A Yes. 09:11:16
Q Okay. And then I'd like to mark as Exhibit 09:11:18
Farlow -- I'm sorry, Farlow Exhibit 2, the 09:11:31
opposition expert report of Martin R. Farlow. 09:11:34
(Exhibit 2 was marked for identification.) 09:11:50
Q And do you recognize this document? 09:11:54
A Yes. 09:12:08
Q Okay. And if you turn to the page after 09:12:09

Page 15

page 48, is that your signature? 09:12:13
A Yes. 09:12:18
Q And this report is dated December 18th, 2009; 09:12:19
correct? 09:12:23
A December 18th, 2009, yes. 09:12:36
Q And so this would have been the expert report 09:12:38
that you submitted in the Namenda patent 09:12:40
litigation; correct? 09:12:43
A Yes. 09:12:46
Q Okay. If you could, turn to paragraph 130 of 09:12:47
this report. 09:12:51
A I'm sorry, which report? 09:12:52
Q Farlow Exhibit 2. 09:12:54
A (The witness complies.) 09:13:09
Q The first clause of the first sentence of 09:13:10
paragraph 130 states "Although, I am not a 09:13:12
medicinal chemist." 09:13:15
Do you see that? 09:13:17
A Yes. 09:13:18
Q What do you understand medicinal chemistry to 09:13:18
include? 09:13:22
A Medicinal chemistry would be, basically, the 09:13:22
creation of chemicals or compounds that are 09:13:30
therapeutically useful. 09:13:33
Q And you do not claim to be a medicinal chemist; 09:13:38

Page 16

right? 09:13:45
A I do not. 09:13:46
Q Are you an expert in pharmacology? 09:13:46
A It's a broad term. I'm not a pharmacologist; 09:13:51
I'm a clinical neurologist. I have knowledge of 09:13:53
pharmacology. 09:14:01
Q Okay. But you would not consider yourself an 09:14:03
expert in pharmacology; correct? 09:14:05
A It's not -- it's not the field I've been 09:14:08
practicing or educated in. It's not what I do 09:14:11
on a daily basis, no. 09:14:14
Q Do you have any experience determining what the 09:14:17
mechanism of action is by which a drug product 09:14:19
works? 09:14:22
A Am I an investigator actively looking at the 09:14:30
mechanisms or deriving the mechanisms or the 09:14:37
associations that occur with drugs? No, on the 09:14:43
basic level. 09:14:49
On the other hand, am I a clinician who has 09:14:51
had -- has been informed of potential mechanisms 09:14:57
of actions of drugs? Has observed the actions 09:15:03
of the drugs in clinical drug trials, and in 09:15:07
clinical practice, and sometimes made inferences 09:15:12
or have opinions about whether a drug works by 09:15:17
one mechanism of action or another? Yes. 09:15:24

Page 17

Q Have you ever undertaken experiments to 09:15:27
determine what the mechanism of action is of any 09:15:29
particular drug? 09:15:32
A No. 09:15:39
Q And have you ever undertaken experiments to 09:15:41
determine what the mechanism of action is of 09:15:44
memantine, in particular? 09:15:48
A Have I personally? 09:16:13
Q Yes. 09:16:15
A Undertaken those mechanisms, no. Have I been 09:16:16
associated with work -- have done reports that 09:16:20
propose different mechanisms of actions for 09:16:28
drugs, yes. 09:16:32
Q And can you describe for me what kind of reports 09:16:32
you've done that propose different mechanisms of 09:16:35
action? 09:16:39
A Not with (verbatim) review of having the 09:16:39
material in front of me. 09:16:43
Q Are these reports that were submitted in the 09:16:45
Namenda patent litigation? 09:16:48
A No. 09:16:49
Q Are these published reports? 09:16:50
A Yes. 09:16:56

[redacted]

Page 54

[redacted]

Q Claim 1 claims, "A composition which influences the central nervous system and is especially useful in the treatment of hyperkinesis, having an active ingredient an effective antihyperkinesic amount of 1-amino-3,5-dimethyladamantane." Do you see that? 10:34:47 10:34:50 10:34:52 10:34:56 10:35:02 10:35:05 10:35:12

A I was not aware of that. 10:35:13

Q And so when you offered your opinions in this case and in the Namenda patent litigation, you were not aware of that; correct? 10:35:14 10:35:18 10:35:23

A Correct. 10:35:24

Q Before 1989, would a person of ordinary skill have known that memantine could be administered orally? 10:35:33 10:35:36 10:35:39

A Yes. 10:35:43

Q And so would you agree that as of April 1989, there was nothing novel about administering memantine orally? 10:35:46 10:35:49 10:35:53

MR. MAJCHRZAK: Objection. Vague. 10:35:56

A Yes. 10:36:11

Q Would you agree that before April 1989, memantine was commercially available in some 10:36:15 10:36:18

Page 55

countries in oral form? 10:36:23

A I don't know the exact dates it was available. It was available in the early '90s in the 19 -- I believe in the 1990s, but I'm not sure of the dates. I would have to review other documents in front of me. 10:36:30 10:36:33 10:36:37 10:36:40 10:36:42

Q Are you familiar with the drug product called -- 10:36:45

A A-k. 10:36:48

Q -- Akatinol? 10:36:50

A Akatinol. Yeah. 10:36:52

Q Okay. 10:36:54

A It's a European product, though; it's not a U.S. product. 10:36:54 10:36:57

Q Right. And were you aware that Akatinol was available in Germany in the 1980s? 10:36:58 10:37:04

A Yes. 10:37:07

Q And do you know the year in which Akatinol became available in Germany? 10:37:09 10:37:15

A No. 10:37:17

Q How did you become aware of Akatinol? 10:37:24

A I believe I first became aware of Akatinol in discussions with -- I'm trying to decide his exact role -- employees of the Merz company when I had interactions with them in the 1990s. 10:37:43 10:37:51 10:38:04 10:38:09

Q And do you remember the name of the Merz 10:38:16

Page 56

employee? 10:38:19

A Moebius. Yeah, I think Hans Moebius. 10:38:24

Q Okay. And would you agree that the active ingredient of Akatinol is memantine? 10:38:32 10:38:35

A I believe they both contain memantine. In terms of whatever other constituents are part of the product, you know, diluents and other additives, I don't know the differences. 10:38:47 10:38:50 10:39:01 10:39:10

Q I would like to go ahead and mark as Farlow Exhibit 6, a document that bears Bates numbers Torrent-Memantine 00008902 through 8909. 10:39:11 10:39:15 10:39:18

(Exhibit 6 was marked for identification.) 10:39:45

Q Are you familiar with this document, Dr. Farlow? 10:40:32

A I've seen it, yes. 10:40:35

Q And this is the Rote Liste; correct? 10:40:38

A Yes. 10:40:44

Q And it's dated 1986; correct? 10:40:45

A Yes. 10:40:50

Q And this is a German document that has been interpreted; correct? 10:40:50 10:40:54

A Yes. 10:40:57

Q And it relates to, if you look at page 906, an entry for Akatinol memantine; do you see that? 10:40:59 10:41:05

A Yes. 10:41:11

Q And it describes under Akatinol memantine 10:41:12

Page 57

tablets; do you see that? 10:41:18

A I do. 10:41:19

Q And it states the composition is "1 tablet contains memantine hydrochloride 10 milligrams." Do you see that? 10:41:20 10:41:24 10:41:29

A Yes. 10:41:30

Q And so do you understand the active ingredient of the drug product Akatinol was memantine, or memantine hydrochloride? 10:41:31 10:41:36 10:41:42

A Yes. 10:41:44

Q And then under "use," do you see that it references organic brain syndrome? 10:41:46 10:41:52

A Yes. 10:42:11

Q And do you see under "use," it also references Parkinson's syndrome? 10:42:12 10:42:16

A Yes. 10:42:22

[redacted]

Page 62

[redacted]

Q Would you agree that it's highly likely that a patient with Alzheimer's disease was given Akatinol before 1989?

A I agree that it's a possibility, but the -- there's a distinction between a patient who has Alzheimer's disease and a patient specifically diagnosed with Alzheimer's disease, and I'm -- I'm -- I'm not sure that the patient specifically diagnosed with Alzheimer's disease was given Akatinol as a therapy for their Alzheimer's disease before 1989.

Q When you say "you agree it's a possibility," are you talking 50/50, 70/30? What kind of possibility?

A I don't -- I don't know.

Page 63

Q You don't know the range of that possibility?

A No.

Q Let's put aside the concept that the patient has to be specifically diagnosed with Alzheimer's disease and talk about a patient that is just diagnosed -- or, sorry -- a patient that has Alzheimer's disease, may or may not be diagnosed.

Would you agree that at least one patient who had Alzheimer's disease was given Akatinol before 1989?

MR. MAJCHRZAK: Objection. Speculation.

A I would -- I would agree that it is a possibility that a patient with Alzheimer's disease was given the Akatinol before 1989.

Q Do you have any opinions about how many -- strike that.

Do you have any opinion about what percentage of patients who had organic brain syndrome had Alzheimer's disease?

A It's such a broad term, organic brain syndrome, and the way it's been used by different physicians in different countries is so -- so variable, and includes so many patients. It's difficult to -- it would be speculative.

Page 64

Q Before April 1989, had you diagnosed patients with Alzheimer's disease in your practice?

A Yes.

Q And what criteria did you use to diagnose patients with Alzheimer's disease in your practice before 1989?

A NINCDS-ADRDA McKhann criteria from 1983 or '84.

Q And were the criteria that you used based on the patient's symptoms?

A The criteria were based on the patient's symptoms, on a clinical evaluation of the patient with cyclometric testing, actually, being obtained on a -- in part of that evaluation -- a physical neurological examination to exclude other systemic causes of cognitive impairment, secondarily causing cognitive impairment, and a neurological examination to help exclude other neurodegenerative conditions, and -- as this was, you're saying, before 1989 --

Q Correct.

A -- would have been an imaging study of the head, at that time, a CT scan of the -- of the brain to specifically exclude structural conditions that might, such as normal pressure

Page 65

hydrocephalus of multiple strokes, et cetera, that might cause dementia.

So -- and those would be the -- the ways in which the information was acquired to then apply the diagnostic criteria, the DSM -- or excuse me -- the NINCDS-ADRDA criteria to make a diagnosis.

Q Did anything in the McKhann criteria require a CT scan of the brain?

A I would like to see the McKhann criteria to answer that specifically. The 1983-'84 criteria, which are not currently used -- or are not used by me in my practice.

Q Do you recall sitting here today whether or not it required a CT scan?

A I believe the goal was to exclude other causes of dementia, and in practice, CT scans at that time were done.

At the time the McKhann criteria were being derived, CT scanning would have been a very young technology, to say the least. I suspect it may not have specifically mentioned CT scans in the original criteria.

[redacted]

Page 94

[redacted]

Q Do you understand that the court construed the term "ineffective amount" to mean an amount shown to cause improvement in comparison to a placebo? 12:08:10 12:08:13 12:08:16 12:08:19

A Yes. 12:08:22

Q And what do you understand the word "improvement" to refer to in the court's claim construction? 12:08:23 12:08:29 12:08:37

A That a patient is therapeutically benefited, has improvement, and has been demonstrated by evidence-based trials in global performance, cognition, and functioning activities of daily living, but that's my -- the -- the language of just improvement, I think, means is clinically beneficial. I don't know that it would necessarily encompass all of those domains. 12:08:39 12:08:54 12:08:57 12:09:03 12:09:08 12:09:19 12:09:23 12:09:26

Q If you look at claim 1 in the patent, which is reexamined claims, the very last page. 12:09:30 12:09:36

A The ex parte reexamination? 12:09:44

Page 95

Q Right. 12:09:50

A Hm? 12:09:50

Q Yes. Correct. 12:09:50

A Okay. 12:09:53

Q So you see claim 1? 12:09:53

A Claim 1. 12:09:54

Q And do you see where claim 1 recites an effective amount? 12:09:55 12:09:57

A Method for prevention or treatment of cerebral ischemia comprising this step of orally administering to a patient diagnosed with Alzheimer's disease an effective amount of the general formula, yes. 12:10:01 12:10:04 12:10:07 12:10:10 12:10:11

Q Okay. And so do you understand effective amount to refer back to the prevention or treatment of a cerebral ischemia? 12:10:14 12:10:17 12:10:21

MR. MAJCHRZAK: Objection. 12:10:32

A Well, prevention or treatment of cerebral ischemia, yes. 12:10:47 12:10:52

Q Turning to -- sorry to flip back to you -- but -- back and forth between exhibits -- but turning to paragraph 51 of Dr. Doody's report. 12:10:55 12:10:58 12:11:02

A 51. Okay. 12:11:06

Q So there's a part of paragraph 51 that continues on to the following page. And towards the 12:11:21 12:11:23

Page 96

middle of that paragraph, she says, "For example, a person weighing 20 kilograms, approximately 44 pounds, and taking 5 milligrams per day would be taking 0.25 milligrams per kilogram. A patient weighing 200 kilograms, approximately 444 pounds, taking 20 milligrams per day would receive a dose of 0.1 milligrams per kilogram." 12:11:27 12:11:30 12:11:33 12:11:36 12:11:40 12:11:44 12:11:48 12:11:52

Do you see that? 12:11:53

A Yes. 12:11:54

Q And do you agree with that statement? 12:11:54

A Yes. 12:12:04

Q Turning to paragraph 54, she states, "Oral administration to patients of memantine hydrochloride at daily doses of 10 milligrams and 20 milligrams per day" -- 12:12:07 12:12:24 12:12:27 12:12:30

A Hold on a second. Hold on a second. 12:12:33

Q Sorry. 12:12:35

A Where are you? 12:12:36

Q It's the sentence starts "As discussed above." 12:12:38

Do you see that? 12:12:41

A Okay. "As discussed." I found it. 12:12:41

Q Okay. So it states, "Oral administration to patients of memantine hydrochloride at daily doses of 10 milligrams and 20 milligrams per day 12:12:44 12:12:48 12:12:51

Page 97

has been shown in clinical studies to benefit global performance, cognition, and function in comparison to placebo treatment." 12:12:54 12:12:56 12:12:59

Do you see that? 12:13:01

A Yes. 12:13:01

Q And do you agree with that statement? 12:13:01

A Yes. 12:13:05

Q And then later in the paragraph, she states, "The persistent activation of the NMDA receptors that is treated by memantine corresponds to the imbalance of neuronal stimulation recited in this claim element." 12:13:07 12:13:13 12:13:18 12:13:22 12:13:26

Do you see that? 12:13:28

A Yes. 12:13:28

Q And do you agree with that statement? 12:13:28

A Yes. 12:13:31

Q Turning to paragraph 73. There's a part of 73 that continues on to the next page. 12:13:50 12:14:09

A (Indiscernibly reading from the document.) Okay. 12:14:13 12:14:28

Q The first full sentence on the next page says "Memantine provides an antagonistic intervention with regard to this excessive inflow of calcium." 12:14:29 12:14:31 12:14:36 12:14:39

Do you see that? 12:14:40

Page 98

A Yes. 12:14:41
Q And do you agree with that statement? 12:14:41
A Yes. 12:14:42
Q And would that statement be true for memantine 12:14:43
administered at 20 milligrams regardless of 12:14:51
whether it was administered before 1989 or after 12:14:57
1989? 12:15:00
A Say what you just said again. 12:15:15
Q Would it be true that memantine provides an 12:15:18
antagonistic intervention with regard to this 12:15:22
excessive inflow of calcium whether or not 12:15:26
memantine was administered before April 1989 or 12:15:30
after April 1989? 12:15:35
A Yes. 12:15:38
Q And wouldn't it be true that oral administration 12:15:47
to patients of memantine hydrochloride, of daily 12:15:50
doses between 10 milligrams and 20 milligrams 12:15:55
per day, would benefit global performance, 12:15:58
cognition, and function whether it had been 12:16:00
administered before 1989 or after 1989? 12:16:03
A Yes. 12:16:20
Q And would oral administration of patients of 12:16:21
memantine hydrochloride at daily doses of 12:16:26
10 milligrams and 20 milligrams per day have 12:16:28
shown the persistent activation of NMDA 12:16:33

Page 99

receptors whether or not it was administered 12:16:37
before April 1989 or after April 1989? 12:16:42
A The persistent say again. 12:16:47
Q Persistent activation of NMDA receptors? 12:16:49
A So I'm sorry, can you repeat the question? 12:17:04
Q Sure. Let me try it again. Is it true that 12:17:07
oral administration of memantine to patients at 12:17:11
daily doses between 10 milligrams and 12:17:16
20 milligrams would have shown persistent 12:17:18
activation of NMDA receptors whether it was 12:17:23
administered before 1989 or after 1989? 12:17:27
A My source of confusion here is persistent 12:17:44
activation of NMDA receptors by excitatory amino 12:17:49
acid and glutamate is the -- contributes to the 12:17:59
symptomatology of Alzheimer's disease. 12:18:03
Memantine doesn't activate the receptors, per 12:18:05
se -- 12:18:08
Q Okay. 12:18:09
A -- it actually blocks that effect. So you're 12:18:09
stating the positive, and I don't know if that's 12:18:13
what you intend to do or what you're doing. 12:18:15
Q Is it true that the oral administration of 12:18:31
memantine to patients at daily doses of 12:18:35
10 milligrams or 20 milligrams per day would be 12:18:38
an effective cerebral ischemia alleviating or 12:18:45

Page 100

preventive amount whether or not it would have 12:18:51
been administered before April 1989 or after 12:18:53
April 1989? 12:18:56
A Yes. 12:19:01
Q Is it true that the oral administration of 12:19:08
memantine to patients at daily doses of 12:19:10
10 milligrams or 20 milligrams per day would 12:19:12
have been provided an antagonistic intervention 12:19:17
with regard to an excessive inflow of calcium 12:19:21
whether or not it was administered before 12:19:24
April 1989 or after April 1989? 12:19:26
A Yes. 12:19:32
MS. JONES: I think now would be a good 12:19:46
time to break for lunch before we go on to 12:19:48
another topic. 12:19:50
THE WITNESS: Okay. 12:19:52
THE VIDEOGRAPHER: We're off the record at 12:19:53
12:19 p.m. 12:19:54
(A lunch recess was taken from 12:19 p.m. 12:19:55
to 12:57 p.m.) 12:19:55

Page 101

AFTERNOON SESSION 12:19:55
THE VIDEOGRAPHER: We are back on the
record at 12:57 p.m.
DIRECT EXAMINATION (Continuing),
QUESTIONS BY MS. MIRANDA JONES:
Q Dr. Farlow, would you agree that oral 12:57:36
administration of memantine at daily doses of 12:57:39
10 milligrams or 20 milligrams per day would 12:57:42
prevent an imbalance of neuronal stimulation 12:57:45
whether it was administered before 1989 or after 12:57:49
April 1989? 12:57:52
A Yes. 12:58:12
Q Would you agree that oral administration of 12:58:13
memantine at daily doses of 10 milligrams or 12:58:16
20 milligrams per day would provide antagonistic 12:58:19
intervention with regard to NMDA receptor 12:58:24
channels whether it was administered before 12:58:28
April 1989 or after April 1989? 12:58:30
A Say it again. 12:58:35
Q Would you agree that oral administration of 12:58:37
memantine at daily doses of 10 milligrams or 12:58:40
20 milligrams per day would provide antagonistic 12:58:44
intervention with regard to NMDA receptor 12:58:49
channels whether it was administered before 12:58:52
April of 1989 or after April of 1989? 12:58:55

Page 102

A So what does "antagonistic intervention" mean? 12:58:58
Q Do you have any understanding of what 12:59:03
"antagonistic intervention" means? 12:59:04
A I understand antagonist, but I don't know how 12:59:07
you're using "intervention." Is it -- you're 12:59:10
using it in implying it has an antagonistic 12:59:13
effect with regard to the receptors, the NMDA 12:59:18
receptors? 12:59:21
Q Correct. 12:59:22
A Yes, I agree. 12:59:23
Q Would you agree that oral administration of 12:59:24
memantine at daily doses of 10 milligrams or 12:59:28
20 milligrams per day would have treated or 12:59:31
eliminated an imbalance of neuronal stimulation 12:59:36
whether it was administered before April 1989 or 12:59:39
after April of 1989? 12:59:43
A Yes. 12:59:46
Q Would you agree that oral administration of 12:59:48
memantine at daily doses of 10 milligrams or 12:59:51
20 milligrams per day would provide an 12:59:54
antagonistic intervention with regard to the 12:59:57
excessive inflow of calcium through NMDA 13:00:00
receptor channels after Alzheimer's disease, 13:00:04
whether it was administered before April 1989 or 13:00:07
after April of 1989? 13:00:09

Page 103

A Let me hear your construction again. 13:00:13
Q Would you agree that oral administration of 13:00:16
memantine at daily doses of 10 milligrams or 13:00:18
20 milligrams per day would provide an 13:00:21
antagonistic intervention with regard to the 13:00:25
excessive inflow of calcium through an NMDA 13:00:28
receptor channel after Alzheimer's disease, 13:00:32
whether it was administered before April of 1989 13:00:36
or after April of 1989? 13:00:39
A So "after Alzheimer's disease," does that mean 13:00:41
associated with Alzheimer's disease? 13:00:46
Q Correct. 13:00:47
A Yes. 13:00:49
Q So, yes, you agree with that statement? 13:00:54
A Yes. 13:00:56
Q Okay. Earlier today we were discussing the 13:00:57
claims of the '703 patent, and I neglected to 13:01:00
ask you about claim 12. So if you could turn 13:01:04
back to the '703 patent. 13:01:07
A The reexamination or the original patent? 13:01:12
Q Claim 12 appears in the original patent, 13:01:14
column 14. 13:01:21
A Okay. 13:01:23
Q All right. And -- 13:01:33
A Okay. 13:01:35

Page 104

Q -- claim 12 recites "wherein the adamantane 13:01:35
derivative in administered in the form of 13:01:38
composition containing the same together with a 13:01:43
pharmaceutically acceptable carrier or diluent." 13:01:45
Do you see that? 13:01:49
A Yes. 13:01:50
Q And would Akatinol dosage form have memantine 13:01:51
administered in the form of a composition 13:01:57
containing memantine with a pharmaceutically 13:02:00
acceptable carrier or diluent? 13:02:03
MR. MAJCHRZAK: Objection. Speculation. 13:02:09
A Yeah, I don't know what the constituents of 13:02:10
Akatinol are. 13:02:16
Q Do you have the Rote Liste? 13:02:18
A It doesn't list any diluents. I don't think. I 13:02:21
could be wrong. 13:02:27
Q So on page 906. 13:02:44
A Okay. 13:02:45
Q It lists the different dosage forms of Akatinol, 13:02:46
and it list tablets as one of the dosage forms. 13:02:49
Do you see that? 13:02:53
A Right. 13:02:54
Q And what do you understand a tablet to be? 13:02:54
A A tablet is composed of a solid, typically a 13:03:01
compressed powder that primarily consists of a 13:03:06

Page 105

drug, but it may have a binder. It may be -- 13:03:10
have a diluent or a form that does not have 13:03:14
pharmaceutical activity that has various 13:03:20
properties that may influence the rate the 13:03:22
tablet will dissolve or the solubility of how it 13:03:27
gets into the system, what the half-life ends up 13:03:34
being. 13:03:37
Q And would a tablet contain a pharmaceutically 13:03:39
acceptable carrier? 13:03:42
A Typically they do. 13:03:46
Q And with respect to the Akatinol memantine 13:03:48
solution, would that include diluent? 13:03:55
MR. MAJCHRZAK: Objection. 13:04:00
A I don't know. All that's listed on this list 13:04:01
that you've presented to -- before me is 13:04:05
memantine hydrochloride for all of the different 13:04:08
forms. It doesn't really specify -- or I don't 13:04:10
see the binder or diluent that may be there. 13:04:13
Q Would you expect the solution to include a 13:04:20
diluent? 13:04:24
MR. MAJCHRZAK: Objection. Speculation. 13:04:26
A It is speculation. I would expect that it 13:04:26
would. 13:04:30

[redacted]

Page 142

Q Okay. In 1985 did you consider organic brain syndrome to include patients diagnosed with Alzheimer's disease? 14:07:08 14:07:18 14:07:20
A Say it again. 14:07:26
Q In 1985 did you consider organic brain syndrome to include patients with Alzheimer's disease? 14:07:28 14:07:36
A In 1985 I had been on faculty at Indiana University for two years and was approached by Dr. Hugh Henry who was the chairman of the department of psychiatry about starting a dementia clinic, which we did. I do not specifically remember thinking about it or discussing the relative relationship between organic brain syndrome and Alzheimer's disease at that time. 14:07:54 14:07:57 14:08:02 14:08:04 14:08:07 14:08:13 14:08:19 14:08:26 14:08:29
Q If you turn to page 92 of the document that's placed before you? 14:08:30 14:08:36
A 92. Okay. 14:08:37
Q Do you see at the bottom around line 22, you were asked a question? 14:08:44 14:08:46
A Okay. 14:08:50
Q "Back in 1985, did you consider organic brain syndrome to include patients diagnosed with Alzheimer's disease?" 14:08:50 14:08:57 14:08:58
Do you see that? 14:08:58

Page 143

A I see it. 14:08:59
Q And your answer is, "Yes"; correct? 14:08:59
A Answered yes. Yes, I did. 14:09:02
Q And so today, do you agree that in 1985 you considered organic brain syndrome to include patients diagnosed with Alzheimer's disease? 14:09:04 14:09:09 14:09:09
A Yes. 14:09:16
Q Okay. Are you aware of any definition of organic brain syndrome that would exclude patients with Alzheimer's disease? 14:09:17 14:09:22 14:09:26
A No. 14:09:27
Q Are you aware of any definition of organic brain syndrome that would not include patients with Alzheimer's disease? 14:09:27 14:09:30 14:09:33
A Any definition of organic brain syndrome that would not include patients diagnosed with Alzheimer's disease? 14:09:42 14:09:43 14:09:45
Q Yes. 14:09:46
A No. Well, to be -- they wouldn't necessarily be diagnosed with Alzheimer's disease, but they may actually have Alzheimer's disease. 14:09:50 14:09:58 14:10:02
Q Looking at page 96, around line 18. You asked -- 14:10:05 14:10:15
A Hold on a second. 14:10:16
Q Sorry. 14:10:17

Page 144

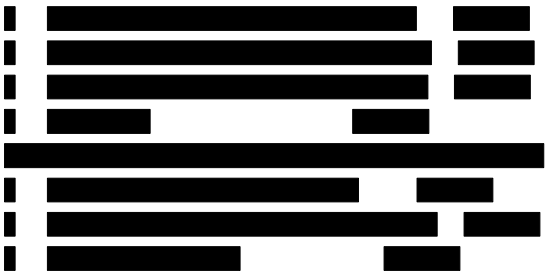
A So is it the pages at the bottom or where's the -- 14:10:18 14:10:22
Q I'm going by the transcript pages. I think that might be easier. So page 96 of the transcript. 14:10:23 14:10:26
MR. MAJCHRZAK: It's in the bottom right-hand corner of that box kind of thing. 14:10:32 14:10:32
A Here (indicating)? 14:10:37
MR. MAJCHRZAK: A little higher. 14:10:38
A Okay. Got it. Got it. Sorry. 14:10:40
BY MS. JONES: 14:10:43
Q Okay. Around line 18? 14:10:43
A Okay. 14:10:46
Q You were asked, "And then how much money" -- I'm sorry -- "And then how much with respect to money that the university received in the form of contracts?" 14:10:47 14:10:49 14:10:53 14:10:54
And you answered, "It's probably approximately one million." 14:10:56 14:10:58
A Okay. 14:11:01
Q And does this refresh your recollection about approximately how much the University of Indiana received in connection with clinical studies that you conducted for Forest? 14:11:01 14:11:04 14:11:07 14:11:11
A What did I say previously here? 14:11:14
Q I think earlier today you testified that you

Page 145

couldn't quite remember. 14:11:21
A I don't remember. So that was probably about right. 14:11:23 14:11:24
Q Okay. And so one million is approximately correct? 14:11:25 14:11:29
A Well, it's probably -- yeah, that would be a lot closer to the time that the money was received. Yeah. 14:11:30 14:11:33 14:11:35
Q All right. Have you completed any neurotransmitter research as of today? 14:11:39 14:11:43
A That's a broad -- what are you referring to by "neurotransmitter research"? 14:12:02 14:12:10
Q Have you done any research in terms of actually studying, I guess, mechanisms of neurotransmitters? 14:12:13 14:12:17 14:12:21
A I've not -- I've not done research that specifically focused on early sedating mechanisms. 14:12:22 14:12:26 14:12:36

[redacted]

Page 190



Q So you would agree that those prior art references disclosed has the effective amount as used in the '703 patent; correct? 15:33:52 15:33:54 15:33:57

A Yes. 15:33:59

Q Okay. And you mentioned a caveat with respect to oral administration of memantine. Would you agree that Ambrozi, Marcea, Tempel, and Schäfer each disclosed oral administration of memantine? 15:34:00 15:34:03 15:34:08 15:34:15

A Yes, they do. I don't -- yes. 15:34:19

Q And when you refer to the IV administration of memantine, you're referring to Fleischhacker; correct? 15:34:24 15:34:29 15:34:33

A Correct. 15:34:33

Q Okay. Do you agree that 20 milligrams of memantine would be considered an effective amount as that term is used in claim 1? 15:34:43 15:35:07 15:35:12

A So what page are the claims on? 15:36:34

Page 191

Q The claims are -- the reexamined claims are at the very back of the patent. And the -- 15:36:36 15:36:41

A Okay. Here we go. (Indiscernibly reading from the document.) And ask your question again. 15:36:52 15:36:59

Q Do you agree that 20 milligrams of memantine per day would be considered an effective amount of memantine as that term is used in claim 1? 15:37:06 15:37:08 15:37:12

A Yes. 15:37:15

Q Okay. And you understand that the court interpreted an "effective amount" to mean an amount shown to cause improvement in comparison to a placebo; correct? 15:37:16 15:37:20 15:37:23 15:37:26

A Yes. 15:37:28

Q Okay. And so do you agree that Ambrozi specifically discloses an amount of memantine that is an effective amount as used in claim 1? 15:37:28 15:37:32 15:37:37

A That's the one paper I don't have. 15:37:54

MR. MAJCHRZAK: No. 11. 15:37:57

A Excuse me. I've got it. Never mind. 15:37:58

Q And so if you look at the bottom of the second column, it notes that Akatinol memantine is being administered in this study; correct? 15:38:00 15:38:04 15:38:12

A Says the doses of memantine and placebo carried out by (indiscernibly reading from the document.) Sometimes -- what is -- where's the dose? 15:38:51 15:38:54 15:39:01

Page 192

Q So it refers to Akatinol memantine? 15:39:11

A Says lot No. 0101? 15:39:15

Q Correct. 15:39:18

A It doesn't tell me the dose though. 15:39:19

Q Do you recall earlier today when you were looking at the Rote Liste that the dose of Akatinol memantine was 20 milligrams per day? 15:39:22 15:39:23 15:39:27

A Akatinol memantine. (Indiscernibly reading from the document.) All right. Dosage. Starts with 10 milligrams in the first week increased by 10 milligrams may be in 20 milligrams per day. 15:39:36 15:40:22 15:40:35 15:40:38

Yes. They say 20 to 30 milligrams per day. The article lists a lot, but I don't see a specific dose listed. 15:40:45 15:40:52 15:40:54

Q And would you understand that the doses of Akatinol started at 10 milligrams per day? 15:40:56 15:40:59

A Yes. 15:41:03

Q Okay. And so would you expect that at least 10 milligrams per day was administered of memantine? 15:41:03 15:41:05 15:41:08

A Yes. 15:41:09

Q Looking at the Fleischhacker reference. 15:41:09

A Okay. Yes. 15:41:13

Q Would you agree that Fleischhacker discloses an effective amount of memantine as that term's used in claim 1? 15:41:15 15:41:19 15:41:23

Page 193

A 20 or 30 milligrams. Yes. 15:41:29

Q Do you agree that Fleischhacker discloses an effective amount that is from 0.01 to 100 milligrams per kilogram? 15:41:35 15:41:42 15:41:46

A Yes. But the -- my understanding is, is the effective amount, as per the Namenda patent, refers to oral medication not to IV, and there may or may not be equivalence to IV. 15:41:53 15:41:57 15:42:03 15:42:07

Q Okay. Do you understand that the only difference between the Fleischhacker reference and claim 1 is the oral administration? 15:42:09 15:42:11 15:42:15

MR. MAJCHRZAK: Objection. 15:42:18

A I do understand that a difference between the Fleischhacker reference and the claim 1 is the oral administration versus the IV administration in the Fleischhacker reports. 15:42:26 15:42:27 15:42:34 15:42:37

Q Do you know of any other differences between claim 1 and the Fleischhacker reference? 15:42:41 15:42:43

A Not sitting here. I can read very carefully and see if something would appear, but that's the one difference that stands out. 15:42:49 15:42:52 15:42:54

Q And so sitting here today, the only difference that you're aware of between the Fleischhacker 15:42:58 15:43:04

Page 194

reference and claim 1 is the oral administration of memantine; correct? 15:43:07 15:43:10

A For the '703, yes. 15:43:17

Q Earlier today, we talked about oral administration; correct? 15:43:20 15:43:22

A We did discuss oral administration. 15:43:25

Q And if I recall correctly, you agreed that oral administration was known in the prior art before April 1989; correct? 15:43:27 15:43:30 15:43:33

A Yes. 15:43:36

Q And so wouldn't it be obvious for a person of ordinary skill in the art to use orally administered memantine in combination with the Fleischhacker reference? 15:43:38 15:43:42 15:43:48 15:43:50

A I would say no. Particularly because the -- in the Fleischhacker study, the results were reported as being negative and not showing any benefit from the drug. The presumed medication -- mechanism of action people generally still talked about a dopaminergic mechanism of action that didn't appear to do anything. 15:43:54 15:44:01 15:44:07 15:44:11 15:44:16 15:44:19 15:44:22 15:44:25

So I'm not sure from the point of view of having a negative IV study why somebody would make the leap and say "It didn't work with IV. 15:44:26 15:44:30 15:44:34

Page 195

Yes, I'm going to go ahead and do a study with an oral medication now." 15:44:37 15:44:41

Q Now, you say the results reported were negative, but isn't it true that Fleischhacker reported results that were inconclusive? 15:44:45 15:44:50 15:44:53

MR. MAJCHRZAK: Objection. 15:44:56

A All right. You can substitute the word "inconclusive" for negative in the previous response to the question. 15:45:08 15:45:10 15:45:17

Q Doesn't Fleischhacker himself suggest that additional studies should be conducted? 15:45:21 15:45:23

A That's kind of a general thing that investigators say when they have a study that is not positive. It doesn't show what they originally wanted to justify, or as to try to continue some enthusiasm for research along similar lines, but, I mean, that's -- that's what I would cite. 15:45:30 15:45:34 15:45:37 15:45:42 15:45:49 15:45:54 15:46:00

Q Specifically, he says "Long-term studies could probably rule out these biases and show clearer distinctions between the two groups"; correct? 15:46:02 15:46:04 15:46:10

A What he's saying is that this is a small trial with relatively small number of patients that makes it difficult to definitively make a statement that the results were negative, that 15:46:13 15:46:17 15:46:19 15:46:23

Page 196

results did not show statistical benefit or didn't show benefit. But you couldn't rule out the possibility that there would be benefit from a longer and better conducted study with more patients. 15:46:31 15:46:36 15:46:38 15:46:43 15:46:46

But, again, the fact that this study was done didn't, you know, even if it's a preliminary study, didn't show anything. The fact that it didn't show anything would be more motivation not to pursue further research, or to administer memantine as our -- or to consider it as going forward in a trial with an incentive to proceed along those lines with an oral medication. 15:46:46 15:46:50 15:46:54 15:46:58 15:47:03 15:47:10 15:47:14 15:47:18 15:47:20

Q Well, do you agree that it showed improvement in both patient groups? And when I say "both patient groups," I mean the patient groups that were given memantine and the control patient group? 15:47:22 15:47:27 15:47:33 15:47:36 15:47:39

A Okay. So improvement, you know, versus what? I mean, it's typically -- in clinical trials you look at how a group of patients who were on medications do versus placebo. You do that because a number of factors may influence the results as they occur in measurements. There 15:47:43 15:47:49 15:47:55 15:48:01 15:48:08 15:48:12

Page 197

may be learning effects that occur. There certainly is -- and particularly with an IV administered medication, there is a -- the potential for a placebo effect as a general rule. The more invasive, as it were, a procedure that's done, and it applies to all basic research, the more aggressive the approach of a therapy is, the more potential there is for placebo effect to believe by the patient and their family that there's some benefit, and there may actually be some benefit for a period of time. 15:48:17 15:48:22 15:48:24 15:48:27 15:48:32 15:48:37 15:48:43 15:48:45 15:48:48 15:48:52 15:48:54 15:48:56

Q Right. And Dr. Fleischhacker reports that no significant differences between the two groups could be calculated by statistical evaluation; correct? 15:48:58 15:49:03 15:49:05 15:49:09

A Correct. 15:49:09

[redacted]

Page 202

[redacted]

Page 204

a person of ordinary skill in the art be 16:00:23
motivated to give memantine to a patient having 16:00:26
Alzheimer's disease? 16:00:32
A The mechanism of action of Akatinol that was 16:00:48
most generally accepted was the dopaminergic 16:00:55
mechanism. The Alzheimer's disease, it was 16:00:59
understood, was not -- was not -- although there 16:01:09
were people suggesting around the edges that 16:01:13
something may have to do with dopaminergic. The 16:01:17
general thought process was that it was 16:01:21
something that had to do with the cholinergic 16:01:24
system. And with regard to Alzheimer's disease 16:01:29
as being a component of organic brain syndrome, 16:01:33
again, it was a component. There were various 16:01:36
other disease processes that were part of 16:01:40
organic brain syndrome. The evidence in terms 16:01:45
of Akatinol, none of that has been discussed 16:01:48
here, is truly by moderate criteria having a 16:01:57
significant beneficial effect in patients with 16:02:04
Alzheimer's disease was, you know, had not 16:02:07
really truly met moderate regulatory criteria. 16:02:14
The studies had not been -- had not been done to 16:02:18
do that. The motivation going forward for all 16:02:22
the reasons that I just elucidated and to do a 16:02:24
study on Alzheimer's disease would have been 16:02:31

[redacted]

Q Is there any -- I guess, so apart from your 15:58:55
opinion that someone would not pursue, I guess, 15:59:04
further development of the Fleischhacker study, 15:59:08
is there any reason that a person of ordinary 15:59:11
skill in the art wouldn't have known about oral 15:59:15
administration of memantine and combined that 15:59:18
with the teachings of Fleischhacker to arrive 15:59:23
at, I guess, essentially what's claimed in 15:59:28
claim 1? 15:59:33
MR. MAJCHRZAK: Objection. 15:59:34
A So I'm not sure what the teachings of 15:59:36
Fleischhacker are that would motivate one to 15:59:40
proceed with oral memantine. It's a study that 15:59:43
had inconclusive results, so it doesn't provide 15:59:47
any motivation to proceed. 15:59:51
Q Let's look at the problem a different way. So 16:00:01
if you start with Akatinol that teaches the oral 16:00:05
administration to patients having organic brain 16:00:11
syndrome and recognize that organic brain 16:00:15
syndrome includes Alzheimer's disease, wouldn't 16:00:19

Page 205

relatively weak, which was why -- or probably 16:02:36
one of the reasons it wasn't done through the 16:02:40
'80s in terms of administering oral, other than 16:02:43
the four trials, the very small pilot trials 16:02:51
that are mentioned. It wasn't something that 16:02:53
was actively pursued in a big study that would 16:02:55
meet regulatory approval by a major 16:02:59
pharmaceutical company during that period of 16:03:02
time. 16:03:04
Q Isn't it true that Merz obtained approval for 16:03:06
Akatinol, its memantine product in Germany, for 16:03:11
use in organic brain syndrome, and then -- 16:03:19
A And the date that that was done? 16:03:27
Q -- and then tried to develop a memantine product 16:03:28
in the United States for an indication that was 16:03:35
defined differently in the United States, but 16:03:37
essentially fell within organic brain syndrome? 16:03:40
MR. MAJCHRZAK: Objection. 16:03:45
A I mean, okay. That's sort of a broad -- that's 16:03:51
a very broad construction. Okay. Akatinol was 16:03:54
approved at a very early date in Germany. The 16:04:01
regulatory that were -- that were applied in 16:04:04
Europe allowed the approval of a lot of 16:04:11
medications with relatively weak evidence by 16:04:13
today's standards. 16:04:16

Page 206

Many of these medications were felt by a person, I think, whatever the phrase is we're using, ordinary skill by psychiatrists and neurologists, not to be truly effective. Memantine was regarded by -- or Akatinol was regarded by many physicians in the same light as -- whatchamacallit -- the plant extract -- Ginkgo biloba -- and was looked at in the same way as something that was given but which is -- they did not regard that as being effective either.

The Merz -- it was a product that Merz had been selling. They were interested in developing the product. Certainly, there was a broad interest amongst pharmaceutical companies that grew -- that grew larger as -- with the development of cholinesterase inhibitors, in particular by pharmaceutical companies in the United States. There was -- there was the -- as it were -- the development of a pathway that they could see for development of drugs that would be approved by FDA, and by that time, the European community regulatory authorities where you could actually -- you knew what the goals were, what the stepping-stones you had to

Page 207

achieve to reach drug approval. And so there was interest in obviously Merz into promoting their drug and interest by Forest in having a potential product, and so they decided in the early to mid-'90s to pursue development of this drug using modern criteria for Alzheimer's disease.

And to see if in that specific subpopulation there really was an effect of the drug as a therapy for Alzheimer's disease.

But with regards -- you know, I think you had some language that sort of said a subset or equate or something. But, I mean, they are sort of different things. Yes, Alzheimer's disease is a subset, but as OBS was applied generally in Europe, and to some extent in the United States, depending upon the country, the locations, and the physicians involved, be it neurologists or psychiatrists. The populations of patients were composed of a big variety of other diagnoses that met, potentially, the criteria for OBS.

And in some places, you know, a big chunk of patients here had schizophrenia, and some may have been traumatic things, and some vascular dementia. It's hard to say what specific -- the

Page 208

etiology of the -- of the symptoms that were classified of OBS, the specific etiologies were.

It was a -- more or less a general wastebasket term that I think -- I mean, honestly, likely inhibited, to some extent, drug development because it had such a heterogenous composition.

Q I want to break that down a little bit. Is it your opinion that in Germany in the early 1980s when Akatinol was approved, physicians didn't distinguish between organic brain syndrome and Alzheimer's disease?

A That would be my opinion.

Q And so if a physician in Germany in the early 1980s had a patient that had Alzheimer's disease, but perhaps wasn't diagnosed with Alzheimer's disease, would that physician have given the patient Akatinol?

MR. MAJCHRZAK: Objection.

A Possibly. I don't know the answer to that question. They -- you know -- you know, the question being did they diagnose the patient as having Alzheimer's disease? And then because they had Alzheimer's, administering Akatinol. I don't know that that was the case.

Page 209

Q But in a jurisdiction where physicians don't separately recognize Alzheimer's disease, is it your opinion that that cannot constitute an invalidating prior use because they didn't make that distinction even though they gave memantine to patients who had Alzheimer's disease?

MR. MAJCHRZAK: Objection. Legal conclusion.

A I kind of lost the question in that.

Q Okay. In a jurisdiction where physicians don't separately recognize Alzheimer's disease from organic brain syndrome, is it your opinion that the use of memantine in that jurisdiction cannot constitute an invalidating prior use because they didn't recognize that they were actually administering memantine to a patient who had Alzheimer's disease?

MR. MAJCHRZAK: Same objection.

A I don't know whether they were administering memantine to patients with Alzheimer's disease or not. They didn't make that diagnosis.

[redacted]

EXHIBIT 276

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

* * * * * * * * * * * * * * *

In Re: *

Namenda Direct Purchaser * C.A. 1:15-cv-07488-CM

Antitrust Litigation *

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HIGHLY CONFIDENTIAL

Video Deposition of James J. Finchen

Tuesday, November 21, 2017

White & Case LLP

75 State Street - 24th Floor

Boston, Massachusetts 02109

---------- J. Edward Varallo, RMR, CRR ----------

Registered Professional Reporter

Page 30

Q. The time is a little off on your email to Mr. Carnevale. It says 1:23 a.m. whereas in Exhibit 2, it was 9:23 a.m. But would you agree that it's the same email? 9:23 p.m. I'm sorry.

MR. TOTO: Yeah, right.

A. Yeah. I mean, I don't know why it's stamped differently.

Q. Were you and Mr. Carnevale in different time zones at the time, if you remember?

A. I don't. I don't remember, yeah.

Q. And if you'd turn to the Medicaid best price analysis that is appended to this document, do you see that the Medicaid best price liability shows a $24 million liability between scenario 1 and scenario 2 over two years?

A. It's closer to --

MR. TOTO: Sorry; hold on. Object to the form. You may answer.

A. I was just going to say it's closer to $25 million, but I do see that.

Q. And between the email that you sent to Mr. Carnevale at 1:23 a.m. or 9:23 p.m., whichever the case may be, and the following most recent in time email in Exhibit 2, which is another email from you to Robert Carnevale twelve hours later, so

Page 31

eleven or twelve hours later, did you work with anyone to try to create an analysis that increased the additional liability between scenario 1 and 2?

MR. TOTO: Object to form, lacks foundation, argumentative, assumes facts, calls for speculation. You may answer.

A. It's hard to say what I did on that day, who I talked to. I would -- I would be hard-pressed to agree with the supposition that we would work to increase the Medicaid liability. I think we were just -- We went through a process of trying to refine the analysis to make sure it reflected the company's, you know, best understanding and reasonable expectations of what should factor into that type of analysis. So it looks like from the Exhibit 2 latest email that there was a revision to the profit share amount or forecast and there was possibly a latest brand projection that was used to update the Medicaid units.

Q. And the profit share is relevant because it's a component of the transfer price. Is that correct?

A. Under scenario 1, that's correct.

Q. And I think you mentioned earlier, is transfer price generally the manufacturing cost plus

Page 32

any royalty or profit share?

MR. TOTO: Under the 2005 agreement, you're asking?

Q. Under the Deficit Reduction Act.

A. So it was my understanding and my role at the time that that's how transfer price should be calculated.

Q. In scenario 2 where Mylan manufactures the authorized generic, there's no transfer price. Is that correct?

A. It was my understanding there would be no transfer price, that is correct.

Q. So profit share is only relevant to scenario 1?

A. In the analysis, that is correct.

Q. And you don't know what the -- You don't have any independent knowledge of what the appropriate number for profit share should be. Right?

MR. TOTO: Object to form, vague and ambiguous.

A. Could you clarify the question?

Q. In scenario 1, do you know if profit share under the contract was 40 percent, a 40/60 split between Forest and Mylan?

Page 33

MR. TOTO: And feel free to look at the analysis if it helps you answer.

A. It does appear to be the case that under the original contract Forest's profit share was 40 percent whereas Mylan's was 60 percent.

Q. But in the analysis that is Exhibit 1 to your declaration, didn't you apply a different profit share arrangement to scenario 1?

A. Again, it's hard to say what we did, you know, nearly eight years ago in this spreadsheet, but I believe if memory serves me correctly that we used the profit share calculations that were in the profit share model or otherwise came from the business development team to calculate the transfer price that was used to calculate in part the Medicaid rebate liability in scenario 1.

Q. And the business development team, did that include Robert Carnevale?

A. It did.

Q. And did that include David Solomon?

A. It did.

Q. And Rachel Mears?

A. It did.

Q. Okay. I'd like to wrap up the deposition with one last line of questioning that

Page 42

Q. Now, can you switch to FRX-AT-04617767, which is the Lexapro market share analysis.
A. I'm there.
Q. Now, do you see a tab, the third tab, which says "Profit per unit calculation new"?
A. I do.
Q. And do you agree that the profit per unit is 52 cents for the first quarter, roughly 62 cents for the second quarter, and roughly 56-1/2 cents for the third quarter?
A. I do agree that's what this shows.
MR. TOTO: And that's all 2012, right?
MR. LITVIN: Yes, that's all 2012.
BY MR. LITVIN:
Q. And those numbers correspond to the profit set forth in the Medicaid liability workbook that we just looked at. Is that correct?
A. They do.
Q. And do the profit figures in this spreadsheet represent Forest's profit per unit on Mylan's sales of authorized generic Lexapro?
MR. TOTO: Object to form.
A. They represent, it appears, the profit per unit that we would've used for the transfer price calculation.

Page 43

Q. And that is in accordance with a profit share percentage arrangement. Is that correct?
MR. TOTO: Object to form.
A. I understand -- It's my understanding that they reflect the profit share arrangement.
Q. Now if you switch to the tab entitled "Auth generic years 1 and 2," you already testified that under scenario 1 and scenario 2 you don't know what the actual agreement says the profit share percentages are. Is that correct?
MR. TOTO: Object to form.
A. I don't know what the actual agreement has, you know, what the drafting of it says and what the requirements of the agreement were.
Q. But under this spreadsheet authorized generic years one and two, does it appear that there is a graduated scale for Mylan from 70 percent to 60 percent and for Forest from 30 to 40 percent?
A. It appears so.
Q. What I'd like you to do is change cells B34 through 36 to 60 percent.
A. B34 through 36 to 60 percent? Okay.
MR. TOTO: Give us a second here.
MR. LITVIN: Sure, take your time. It is 60 percent already.

Page 44

MR. LITVIN: Under the tab "Authorized generic years 1 and 2."
MR. TOTO: Oh, okay.
(Pause)
MR. LITVIN: Just let me know when you're ready, counsel. I'm just waiting for --
THE WITNESS: I'm ready.
MR. LITVIN: Okay.
BY MR. LITVIN:
Q. And then if you change, I'll ask you to change B38 to B40 to 40 percent.
A. Okay.
Q. Now if you switch back to the third tab, "Profit per unit calculation new" --
A. Okay.
Q. -- now you see that the profit per unit is now 69.3, roughly 69.3 cents for the first and second quarters?
A. I do.
Q. So by changing the profit share to 60 percent for Mylan and 40 percent for Forest, we've increased the Forest profit and therefore the transfer price. Is that correct?
A. We have.
Q. Now if you could switch back one more

Page 45

time to the other spreadsheet, which is the Medicaid best price spreadsheet ending in 768.
A. Mm-hmm, okay.
MR. TOTO: Give us a second here, counsel.
MR. LITVIN: Yes.
(Pause)
MR. TOTO: Okay.
BY MR. LITVIN:
Q. And if you could go to the BP calc tab and if you could replace the profit numbers in S14, 16 and 18 with 0.69347.
MR. TOTO: 16?
MR. LITVIN: 14, 16 and 18.
(Pause)
THE WITNESS: Okay.
MR. TOTO: Hold on. Give us a second, counsel.
MR. LITVIN: You want me to repeat the -- ?
MS. O'SHAUGHNESSY: No, I have it, I think. Okay.
BY MR. LITVIN:
Q. And in addition, if you could change T14, T16 and T18 to 0.69347. And so to clarify what

Page 46

we just did, we changed the profit share in the Medicaid spreadsheet to reflect the same profit per unit that we changed in the Lexapro generic analysis.

MR. TOTO: Object to form, lacks foundation, and this whole exercise assumes that nothing else would have changed under this hypothetical world where we're changing just parts of these spreadsheets on the fly. But you may answer.

A. Yes, we have, so I agree with what you said that we changed, yes.

Q. And just to clarify, all we've changed is the profit share arrangement, is that correct, reflected in off generic year one and two?

A. That would -- That appears to be the case.

Q. If you now switch to the tab titled Liability under the Medicaid liability sheet, the additional liability decreases from 30,437,000 to 28,550,000. Is that correct?

A. It is.

MR. TOTO: Hold on. Give me a second.

MR. LITVIN: Sure, take your time.

MR. TOTO: So you're comparing what you

Page 47

changed to what? To the original which was Exhibit 1 of his declaration. Is that right?

MR. LITVIN: Yes.

MR. TOTO: All right, let me just....

BY MR. LITVIN:

Q. So just to clarify --

MR. TOTO: Okay, I just want to check it. Okay.

BY MR. LITVIN:

Q. Just to clarify, there's a line on this liability spreadsheet that says "Additional liability for scenario 1 versus scenario 2" and then there's a number. Correct?

A. That is correct.

Q. And the number dynamically updated to reflect the changes that we made. Is that correct?

A. That is correct.

Q. And applying the royalty rate change that we just did results in a decrease in the savings, Medicaid liability savings in this analysis, by roughly 1,887,000. Is that correct?

MR. TOTO: Object to form, same reasons as my prior objection.

A. That's correct.

Q. And I wonder if you can tell if that

Page 48

same 1,887,000 difference would hold if we just focused on the first five quarters, so quarter one 2012 through quarter one 2013?

A. So can you please clarify -- ?

MR. TOTO: Please hold on. Go ahead.

A. Could you please clarify what you're asking?

Q. Yes. So the liability spreadsheet shows the additional liability savings for quarter one 2012 through quarter one 2014. Correct?

A. That is correct.

Q. And we made some changes and pursuant to those changes, the liability savings is $1.887 million less. Is that correct?

MR. TOTO: Object to form.

Q. Over the course of the entire period of analysis, which is Q1 '12 through Q1 '14. Is that correct?

A. Yes, but it's still $28-1/2 million, a little more than that.

Q. Yes. And I just wanted to -- Strike that. If you just focused on the first five quarters, which is Q1 2012 through Q1 2013 --

A. Okay.

Q. -- would the savings also be under the

Page 49

changes we made $1.887 million less?

A. It should not have affected any quarters other than the ones that we changed.

Q. And that's because -- Well, that's because the best price for the subsequent quarters has not been changed. Is that correct?

A. That is correct.

MR. LITVIN: Okay, I have no further questions at this time.

MR. TOTO: Okay. I have a few questions.

EXAMINATION

BY MR. TOTO:

Q. So just picking up where we left off here with all these changes that counsel asked you to do on the fly here on the spreadsheets, what is the total amount of savings that Forest would have realized on best price from switching the manufacturing of the generic Lexapro, authorized generic Lexapro, from Forest to Mylan?

MR. LITVIN: Objection, leading. And over the entire period of time or just the first five quarters?

BY MR. TOTO:

Q. Can you answer the question?

2012." Did I read that correctly?
A. Yes, you did.
Q. Is that a true and accurate statement?
A. It is.
Q. "D, Forest's expected cost of goods sold, COGS, to provide finished authorized generic Lexapro product to Mylan under scenario 2, which impacts the net transfer" -- I think I misread that, so let me start again. This is Section 13(d) of your declaration talking about the key assumptions: "Forest's expected cost of goods sold, COGS, to provide finished authorized generic Lexapro product to Mylan under scenario 1, which impacts the net transfer price. I was provided with information that Forest's COGS would be the API price plus the manufacturing cost plus the packaging cost." Did I read that correctly?
A. You did.
Q. Is that a true and accurate statement?
A. It is.
Q. 13(e), "For iterations of the model after January 14, 2010, calculation of expected profit share payments from Mylan to Forest in scenario 1, which impacts the net transfer price. Bob Carnevale provided this information to me based

upon the Lexapro generic analysis forecasts, an example of which can be found at FRX-AT-04617114, attached hereto as Exhibit 2." Did I read that correctly?
A. You did.
Q. Is that a true and accurate statement?
A. It is.
Q. "Expected quarterly change in CPI, the Consumer Price Index, which affects the average rebate per unit, RPU." And that was Section 13(f) of your declaration. Did I read that correctly?
A. You did.
Q. Is that a true and accurate statement?
A. It is.
Q. Okay.
Section paragraph 14 of your declaration reads: "Between January 2010 and March 2010, I created more than ten iterations of the Lexapro Medicaid best price liability analysis as I received updated information on assumptions, including Lexapro unit and price forecasts, transfer price and profit share. To the best of my recollection, in each case I calculated that Forest would incur at least 20 million less in Medicaid best price liability under scenario 2 as compared to scenario

1." Did I read that correctly?
A. You did.
Q. Is there anything in today's deposition that causes you to believe that that is no longer an accurate statement?
A. No.
Q. Paragraph 15: "To the best of my knowledge, based on my review of several versions of the analysis, Exhibit 1 appears to be the latest Lexapro Medicaid best price analysis conducted in advance of execution of the Lexapro amendment on July 21, 2010, and it appears to reflect the final assumptions and inputs available at that time. Exhibit 1 forecasts that Forest would have reduced its Medicaid best price liability by $30.4 million under scenario 2 as compared to scenario 1. Further, this calculation does not include the additional best price liability savings Forest would accrue in the event that Mylan continued to manufacture and sell an authorized generic version of Lexapro for longer than nine quarters." Did I read that correctly?
A. You did.
Q. Is that a true and accurate statement?
A. It is.

Q. To the best of your knowledge, sir, what was the purpose for which this best price analysis that you talk about in your declaration was created?
A. To evaluate a proposed change in the arrangement with Mylan.
Q. Are you aware of any effort to prepare fake or fraudulent forecasts at Forest?
A. No.
MR. TOTO: I have no further questions.
MR. LITVIN: Two follow-up questions.
FURTHER EXAMINATION
BY MR. LITVIN:
Q. With reference to paragraph 15, are you sure that Exhibit 1 to your declaration used accurate profit share assumptions to arrive at the $30.4 million savings between scenario 1 and scenario 2?
MR. TOTO: Object to form.
A. I can't speak to the profit share assumptions. They were provided to me by folks that had experience analyzing those deals and I relied on their experience to prepare those assumptions. And, I mean, maybe you could talk to those people.
Q. Robert Carnevale?
A. Yes.

EXHIBIT 277

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION	Case No. 1:15-CV-07488-CM-JCF

DECLARATION OF JAMES FINCHEN

I, James Finchen, hereby declare as follows:

1. I am currently employed at Alkermes, Inc. as Director, Contracts Counsel. My current responsibilities include providing legal advice to the Government Pricing, Payer, and Trade functions, as well as overseeing the U.S. Contracting function.

2. I was employed by Forest Laboratories, Inc. ("Forest") from October 2000 until March 2014.

3. From October 2000 through June 2006, I held various positions in the Sales Administration department.

4. From July 2006 through May 2010, I worked in the Commercial and Government Contracting group as an Associate Manager of Contract Development and Analysis (July 2006 – June 2007), a Manager of Contract Development and Analysis (July 2007 – June 2009), and a Senior Manager of Contract Development and Analysis (July 2009 – May 2010). My responsibilities within the Commercial and Government Contracting group included overseeing calculation of government rebates and pricing, and developing contracts for various trade channels (such as PBMs, Medicaid, Medicare, and GPOs).